IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

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| CHRISTA BLEVINS-ELLINGTON, KIMYANIA SMITH, AMANDA JO VENENGA & DAVID RAYMOND VENENGA,<br><br>Plaintiffs,<br><br>v.<br><br>COOPERSURGICAL, INC.; THE COOPER COMPANIES, INC.; FEMCARE, LTD., U.K. SUBSIDIARY OF UTAH MEDICAL PRODUCTS & UTAH MEDICAL PRODUCTS,<br><br>Defendants. | : | CIVIL ACTION NO.<br>1:22-CV-00197-LMM |

**ORDER**

This case comes before the Court on Defendants' Motions to Dismiss [24, 25, 26, 55] Plaintiffs' Second Amended Complaint [17]. After due consideration, the Court enters the following Order:

## I. BACKGROUND

Plaintiffs are three women and one of their spouses who allege that Defendants designed, manufactured, and advertised defective "Filshie Clips," which caused significant physical injuries when the clips migrated. Dkt. No. [17]. Defendants are The Cooper Companies, Inc. ("Cooper Companies"); CooperSurgical, Inc. ("CooperSurgical"); Utah Medical Products, Inc. ("Utah

Medical"); and Femcare, Ltd. ("Femcare"), Utah Medical's United Kingdom subsidiary. Id. ¶¶ 5–10.

Filshie Clips are a birth control device used in tubal ligation procedures. Id. ¶¶ 17–18. They are small titanium clips lined by silicone rubber that are meant to be attached to the fallopian tubes. Id. ¶ 19. When they function properly, Filshie Clips exert continuous pressure to block the fallopian tubes and serve as a long-term form of birth control. Id. ¶¶ 20, 22.

Defendant Femcare, a manufacturer, received conditional premarket approval ("PMA") for Filshie Clips from the Food and Drug Administration ("FDA") in 1996 as a Class III device, the most dangerous and most rigorously tested class of medical devices. Id. ¶¶ 23–25; 21 U.S.C. §§ 360c, 360e. At that time, Defendants reported that Filshie Clips had a .13% migration rate. Dkt. No. [17] ¶ 49. Plaintiffs argue that the risk of migration was significantly higher than that number and has continued to climb since 1996, today reaching an estimated 25% migration rate. Id. ¶¶ 44, 50. Stated succinctly, Plaintiffs' suit alleges that Defendants designed and manufactured a defective product and failed to warn both consumers and healthcare providers about this risk of migration—of which Defendants were or should have been aware—and that with proper disclosures of the migration risks, Plaintiffs' injuries would have been avoided. Id. ¶¶ 46–48, 50–54.

Plaintiffs Christa Blevins-Ellington, Kimyania Smith, and Amanda Jo Venenga each underwent tubal ligation procedures using Filshie Clips between

2011 and 2013. Id. ¶¶ 55–56, 63–64, 74–75. Before their procedures, each Plaintiff received a consent form that only discussed risks associated with the procedure—not risks associated with Filshie Clips themselves, meaning that Plaintiffs were not advised of the risk of post-surgery Filshie Clip migration. Id. ¶¶ 57, 65, 76. Further, Plaintiffs claim that the product information sheets provided to Plaintiffs' healthcare providers did not include the alleged actual migration rate (25%) of Filshie Clips. Id. ¶¶ 58, 66, 77. Plaintiffs argue that this omission was critical because the Filshie Clips used in all three Plaintiffs migrated from their original locations, causing severe injuries and requiring further surgeries in attempts to remove their clips. Id. ¶¶ 59–62, 67–73, 78–84. Plaintiffs' injuries include stabbing pains, menstrual changes, anemia, heart palpitations, high blood pressure, nerve issues, brain fog, panic attacks, and more. Id. ¶¶ 59, 67–68, 78. Because of these injuries, Amanda Jo Venenga's husband, Plaintiff David Raymond Venenga, also seeks relief for loss of consortium and pain and suffering that he claims to have endured while observing his wife's pain.[1] Id. ¶¶ 80, 84.

Based on these facts, Plaintiffs bring seven substantive counts against all Defendants, plus pleas for punitive damages (Count 8) and attorney's fees (Count 9). Id. ¶¶ 97–194. The seven substantive counts are as follows: Count 1: Design Defect, Count 2: Manufacturing Defect, Count 3: Failure to Warn, Count 4: Strict

[1] The Court notes that Plaintiffs' Second Amended Complaint also lists Marcous Ford as a party to the action. The Court granted Plaintiffs' unopposed motion to remove Mr. Ford from the action [53] on November 22, 2022. Dkt. No. [54]. Thus, Mr. Ford is no longer a party, but these pleadings otherwise remain unaffected.

Liability, Count 5: Negligence, Count 6: Violation of Consumer Protection Laws, and Count 7: Gross Negligence. Id. ¶¶ 97–182.

All four Defendants move to dismiss Plaintiffs' Complaint on various grounds. Defendants Cooper Companies, Utah Medical, and Femcare first argue that (a) this Court cannot exercise personal jurisdiction over them and that (b) venue is improper. Dkt. No. [24] at 8–17; Dkt. No. [25] at 8–16; Dkt. No. [55] at 8–21. Alternatively, Cooper Companies and Utah Medical argue that (c) they cannot be held liable for their subsidiaries' conduct, even if they are subject to this Court's jurisdiction. Dkt. No. [24] at 18–19; Dkt. No. [25] at 18–19. Next, all Defendants contend that (d) federal law preempts Plaintiffs' claims, that (e) the learned intermediary doctrine precludes liability here, and that (f) the applicable statute of repose bars Plaintiff Smith's strict liability claim. Dkt. No. [24] at 20–31; Dkt. No. [25] at 19–30; Dkt. No. [26] at 7–18; Dkt. No. [55] at 21–28.

## II. LEGAL STANDARD

Given the range of Defendants' arguments, multiple legal standards apply. First, three Defendants contest personal jurisdiction under Rule 12(b)(2) and venue under Rule 12(b)(3). And second, all four Defendants argue for dismissal under Rule 12(b)(6).

### A. Rule 12(b)(2)

Federal Rule of Civil Procedure Rule 12(b)(2) allows a defendant to challenge a plaintiff's claim by filing a motion to dismiss for lack of personal jurisdiction. Fed. R. Civ. P. 12(b)(2). "A plaintiff seeking the exercise of personal

jurisdiction over a nonresident defendant bears the initial burden of alleging in the complaint sufficient facts to make out a prima facie case of jurisdiction." Diamond Crystal Brands, Inc. v. Food Movers Int'l, Inc., 593 F.3d 1249, 1257 (11th Cir. 2010) (quoting United Techs. Corp. v. Mazer, 556 F.3d 1260, 1274 (11th Cir. 2009)); accord Posner v. Essex Ins. Co., 178 F.3d 1209, 1214 (11th Cir. 1999). "The court construes the allegations in the complaint as true to the extent that they are uncontroverted by defendant's evidence." Paul, Hastings, Janofsky & Walker, LLP v. City of Tulsa, 245 F. Supp. 2d 1248, 1253 (N.D. Ga. 2002).

If the defendant challenges the plaintiff's allegations of jurisdiction and supports the challenge with affidavit evidence, the burden shifts back to the plaintiff to produce evidence supporting jurisdiction. Id. at 1257. "Where the plaintiff's complaint and supporting evidence conflict with the defendant's affidavits, the court must construe all reasonable inferences in favor of the plaintiff." Id. (quoting Meier ex rel. Meier v. Sun Int'l Hotels, Ltd., 288 F.3d 1264, 1269 (11th Cir. 2002)). Motions to dismiss for lack of personal jurisdiction filed at the pleading stage should "be treated with caution" and granted only if the plaintiff has failed to allege "sufficient facts . . . to support a reasonable inference that the defendant can be subjected to jurisdiction within the state." Bracewell v. Nicholson Air Servs., Inc., 680 F.2d 103, 104 (11th Cir. 1982).

"[A] federal court sitting in diversity undertakes a two-step inquiry in determining whether personal jurisdiction exists: the exercise of jurisdiction must (1) be appropriate under the state long-arm statute and (2) not violate the Due

Process Clause of the Fourteenth Amendment to the United States Constitution." Diamond Crystal, 593 F.3d at 1257–58 (quoting Mazer, 556 F.3d at 1274). District courts in Georgia should take care not to conflate these two inquiries because Georgia's long-arm statute does not provide personal jurisdiction that is coextensive with due process. Id. at 1259. Instead, the long-arm statute "imposes independent obligations that a plaintiff must establish for the exercise of personal jurisdiction that are distinct from the demands of procedural due process." Id.

**B. Rule 12(b)(3)**

Federal Rule of Civil Procedure 12(b)(3) allows dismissal for improper venue. Fed. R. Civ. P. 12(b)(3). Venue is proper (1) in a district where any defendant resides if all defendants reside in the district's state, (2) in a district where a substantial part of the events giving rise to the claim took place or where a substantial part of the property subject to the dispute is located, or (3) in a district in which any defendant is subject to personal jurisdiction if there is no district otherwise available. 28 U.S.C. § 1391(b). On a Rule 12(b)(3) motion, the plaintiff has the burden of showing that venue in the forum is proper. Delong Equip Co. v. Wash. Mills Abrasive Co., 840 F.2d 843, 845 (11th Cir. 1988); Wai v. Rainbow Holdings, 315 F. Supp. 2d 1261, 1268 (S.D. Fla. 2004) (collecting cases). The court must accept all allegations in the complaint as true unless the defendants contradict them with affidavits. Wai, 315 F. Supp. 2d at 1268. When an allegation is challenged or contradicted, the court may consider matters outside the pleadings, "particularly when the motion is predicated upon key issues of fact." Id. (quoting

Webster v. Royal Caribbean Cruises, Ltd., 124 F. Supp. 2d 1317, 1320 (S.D. Fla. 2000)). The court must draw all reasonable inferences and resolve all factual conflicts in the plaintiff's favor. Id.

**C. Rule 12(b)(6)**

Federal Rule of Civil Procedure 8(a)(2) requires that a pleading contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). While this pleading standard does not require "detailed factual allegations," the Supreme Court has held that "labels and conclusions" or "a formulaic recitation of the elements of a cause of action will not do." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007)).

To withstand a Rule 12(b)(6) motion to dismiss, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Id. (quoting Twombly, 550 U.S. at 570). A complaint is plausible on its face when a plaintiff pleads factual content necessary for a court to draw the reasonable inference that the defendant is liable for the conduct alleged. Id. (citing Twombly, 550 U.S. at 556).

At the motion to dismiss stage, "all well-pleaded facts are accepted as true, and the reasonable inferences therefrom are construed in the light most favorable to the plaintiff." FindWhat Inv. Grp. v. FindWhat.com, 658 F.3d 1282, 1296 (11th Cir. 2011) (quoting Garfield v. NDC Health Corp., 466 F.3d 1255, 1261 (11th Cir.

2006)). But this principle does not apply to legal conclusions set forth in the complaint. Iqbal, 556 U.S. at 678.

## III. DISCUSSION

To reiterate, Defendants make various arguments for dismissal that can be labeled as follows: (A) personal jurisdiction, (B) venue, (C) parent company liability, (D) preemption, (E) learned intermediary doctrine, and (F) statute of repose.[2] Defendants Cooper Companies and Utah Medical argue all six points (A–F), and Defendant CooperSurgical joins them in arguing the final three issues (D–F). Defendant Femcare argues all but (C) parent company liability. Plaintiffs challenge all of these arguments except for (F) the statute of repose. The Court addresses each issue in turn.

### A. Personal Jurisdiction

First, Defendants Cooper Companies, Utah Medical, and Femcare assert that the Court does not have personal jurisdiction over them, requiring dismissal of the claims against them. Dkt. No. [24] at 8–14; Dkt. No. [25] at 8–14; Dkt. No. [55] at 8–18. In Plaintiffs' Complaint, they allege that Defendants are subject to this

[2] Defendant CooperSurgical also alleges that Plaintiffs' Complaint is a shotgun pleading because all claims are asserted against all Defendants without distinction. Dkt. No. [26] at 18–19; Dkt. No. [33] at 14–15. The Court disagrees. Although Plaintiffs did not separate each claim by Defendant, Plaintiffs' Complaint is sufficient "to give the defendants adequate notice of the claims against them and the grounds upon which each claim rests," as evidenced by Defendants' detailed Motions to Dismiss. Weiland v. Palm Beach Cnty. Sheriff's Off., 792 F.3d 1313, 1323 (11th Cir. 2015). Thus, the Court will not dismiss Plaintiffs' Complaint, or require repleading, on shotgun grounds.

Court's jurisdiction because of their Filshie Clip business in Georgia. Dkt. No. [17] ¶¶ 13–15. In response to Defendants' Motions to Dismiss on personal jurisdiction grounds, Plaintiffs contend that Utah Medical is subject to the Court's jurisdiction based on its current contacts with Georgia, Dkt. No. [29] at 14–19; that Femcare has sufficient business contacts with Georgia to support jurisdiction, Dkt. No. [56] at 13–24; and that both Utah Medical and Cooper Companies could be subject to the Court's jurisdiction through their respective subsidiaries' contacts with Georgia, Dkt. No. [29] at 17–23; Dkt. No. [28] at 14–22. The Court's jurisdictional analysis proceeds in four parts: first, applicable Georgia and federal law regarding personal jurisdiction; second, jurisdiction over Defendant Utah Medical; third, jurisdiction over Defendant Cooper Companies; and fourth, jurisdiction over Defendant Femcare.

### *1. Personal Jurisdiction Standard*

Personal jurisdiction entails compliance with both the forum state's long-arm statute and constitutional due process requirements. Thus, the Court must determine first whether Georgia's long-arm statute would permit personal jurisdiction over Defendants and then ensure that exercising jurisdiction over them would not run afoul of constitutional limitations. Under the Georgia long-arm statute, "[a] court of this state may exercise personal jurisdiction over any nonresident . . . in the same manner as if he or she were a resident of this state, if in person or through an agent, he or she . . . [t]ransacts any business within this state." O.C.G.A. § 9-10-91(1). This provision grants personal jurisdiction to the

maximum extent permitted by due process, without regard to whether the defendant is physically present in Georgia. Innovative Clinical & Consulting Servs., LLC v. First Nat'l Bank of Ames, 620 S.E.2d 352, 355 (Ga. 2005); see also Diamond Crystal, 593 F.3d at 1261 (explaining that due process limits the reach of personal jurisdiction under O.C.G.A. § 9-10-91(1) but that the two standards are not "coextensive").

"'[T]ransacts any business' requires that the nonresident defendant has purposefully done some act or consummated some transaction in Georgia." Diamond Crystal, 593 F.3d at 1264 (cleaned up). Courts thus consider a nonresident's both tangible and intangible conduct, such as "mail, telephone calls, and other 'intangible' acts"—even if they occurred outside of Georgia—to determine "whether it can fairly be said that the nonresident has transacted any business within Georgia." Id.; see also id. at 1264 n.18 (finding "instructive the literal definition of the words in the statute" and providing the definitions of "transact," "any," and "business" from Webster's Third New Int'l Dictionary (1993)); Lima Delta Co. v. Glob. Aerospace, Inc., 752 S.E.2d 135, 139–40 (Ga. Ct. App. 2013) (noting that post-Innovative Clinical, long-arm jurisdiction may be "based on business conducted by the defendant or its agent 'through postal, telephonic, and Internet contacts'" (quoting ATCO Sign & Lighting Co. v. Stamm Mfg., Inc., 680 S.E.2d 571, 576 (Ga. Ct. App. 2009))).

Corporate defendants may be brought into court through either general or specific jurisdiction. General jurisdiction applies when a corporation is "at home"

in the forum state, typically meaning that the corporation is either incorporated in or houses its principal place of business in the forum state. Daimler AG v. Bauman, 571 U.S. 117, 137 (2014). Plaintiffs do not dispute that general jurisdiction is unavailable here because Georgia is not the state of incorporation or the principal place of business for any Defendant. Dkt. No. [17] ¶¶ 5–10.

Instead, the parties dispute specific jurisdiction. If a nonresident does business in the state, in accordance with the Georgia long-arm statute, due process provides the outer limits of jurisdiction over that defendant: the defendant must have sufficient contacts with the forum state such that hearing the suit would not undermine due process. Internet Sols. Corp. v. Marshall, 557 F.3d 1293, 1295–96 (11th Cir. 2009). This due process analysis generally entails three prongs: (1) the plaintiff's claims relate to or arise out of the defendant's contacts with the forum, (2) the defendant purposefully availed itself of the privileges of doing business in the forum, and (3) exercising jurisdiction would not offend notions of fair play or substantial justice. Louis Vuitton Malletier, S.A. v. Mosseri, 736 F.3d 1339, 1355 (11th Cir. 2013).

Plaintiffs also argue that Defendants Utah Medical and Cooper Companies are subject to the specific jurisdiction in this Court based on their subsidiaries' contacts with the forum state—i.e., alter ego jurisdiction. For jurisdiction under this theory, Plaintiffs must show two things: first, that the subsidiaries' contacts with Georgia would permit specific jurisdiction, and second, that Utah Medical and Cooper Companies are sufficiently intertwined with Femcare and CooperSurgical

respectively, making it appropriate to impute the subsidiaries' Georgia contacts to their parent corporations. See United States ex rel. Bibby v. Mortg. Invs. Corp., 987 F.3d 1340, 1355 (11th Cir. 2021).

Under Eleventh Circuit precedent, "where the apparent forum contacts of one actor are really the forum contacts of another, it is consistent with due process to impute those contacts for personal jurisdiction purposes." Id. (citing Meier, 288 F.3d at 1272). In other words, "it is compatible with due process for a court to exercise personal jurisdiction over an individual or a corporation . . . when the individual or corporation is an alter ego or successor of a corporation that would be subject to personal jurisdiction in that court." Id. (quoting Patin v. Thoroughbred Power Boats Inc., 294 F.3d 640, 653 (5th Cir. 2002)). Some factors that may evidence a corporate alter ego include the level of control exerted over the local entity, the use of corporate formalities, commingled assets, and other agency principles. Id. at 1355–56.

But in cases where the "subsidiary's presence in the state is primarily for the purpose of carrying on its own business and the subsidiary has preserved some semblance of independence from the parent, jurisdiction over the parent may not be acquired on the basis of the local activities of the subsidiary." Consol. Dev. Corp. v. Sherritt, Inc., 216 F.3d 1286, 1293 (11th Cir. 2000) (citation omitted). Further, "as long as a parent and a subsidiary are separate and distinct corporate entities, the presence of one in a forum state may not be attributed to the other." Id. In short, only when a subsidiary is fully dependent on or acting as the agent of its

parent company can the alter ego theory support a court's exercise of personal jurisdiction over a foreign parent company.

***2. Utah Medical Products, Inc.***

In its Motion to Dismiss, Defendant Utah Medical asserts that it is not subject to this Court's jurisdiction because it did not have any related contacts with Georgia or the physicians who used Filshie Clips in the state at the time relevant to Plaintiffs' claims; therefore, it claims that exercising jurisdiction over Utah Medical would violate due process. Dkt. No. [25] at 8–9. Further, Utah Medical alleges that even if it now has any contacts with Georgia, there is no nexus between its current contacts and this litigation because it did not have sufficient contacts with the state at the time of Plaintiffs' surgeries, such that Plaintiffs' claims might "arise out of" those contacts. Id. at 12–14. Plaintiffs respond that personal jurisdiction over Utah Medical is proper either on its own current contacts or as Defendant Femcare's alter ego. Dkt. No. [29] at 14–23. The Court evaluates these arguments in the traditional personal jurisdiction framework: first, the state's long arm statute, and second, constitutional due process protections.

**a. Georgia Long-Arm Statute**

First, Utah Medical argues that the Court can disregard Georgia's long-arm statute because due process bars the Court from exercising jurisdiction here, but it also contends that even when looking to the long-arm statute, Plaintiffs still failed to show the necessary contacts with Georgia. Dkt. No. [25] at 11. The Court disagrees. Utah Medical's post-2019 business in Georgia satisfies the Georgia long-

arm statute. Plaintiffs provide that Utah Medical acquired Femcare in 2011 and that Femcare manufactures Filshie Clips. Dkt. No. [29] at 14. The parties do not dispute that in 2019 Defendant Utah Medical bought the U.S. distribution rights for Filshie Clips from Defendant CooperSurgical, and Defendants admit that Utah Medical and Femcare both now distribute the clips. Dkt. No. [33] at 7. Further, Plaintiffs claim that Utah Medical's current advertising constitutes business in Georgia related to Plaintiffs' claims because they discovered their injuries after these contacts began. Dkt. No. [29] at 15–16.

The text of the Georgia statute requires only that a foreign defendant "transacts any business within this state." O.C.G.A. § 9-10-91(1). Although Utah Medical implies that it may not have specific contacts in Georgia through its new distributor role, it does not actually challenge Plaintiffs' contention that it currently does business in Georgia. Dkt. No. [33] at 13–14. Instead, Utah Medical asserts that its post-2019 contacts are irrelevant, id. at 13, but the Court is not persuaded by that assertion.

The Eleventh Circuit and the Georgia Supreme Court have construed the Georgia long-arm statute in its "literal" sense, meaning that the statute has a broad reach, which grants Georgia courts jurisdiction over any nonresident defendant who voluntarily does business in the state. Diamond Crystal, 593 F.3d at 1259; Innovative Clinical, 620 S.E.2d at 355. By that definition, Utah Medical has purposefully conducted business in Georgia since at least 2019, according to the facts presented and drawing all reasonable inferences in the light most favorable to

Plaintiffs. Diamond Crystal, 593 F.3d at 1257. Therefore, Georgia law confers the Court with long-arm jurisdiction over Defendant Utah Medical.

**b. Due Process**

Having satisfied the long-arm statute, due process next requires that three elements be met: (1) Plaintiffs' claims must "'arise out of or relate to' at least one of the defendant's contacts with the forum"; (2) Utah Medical must have "purposefully availed" itself "of the privilege of conducting activities within the forum state, thus invoking the benefit of the forum state's laws;" and (3) the Court's exercise of personal jurisdiction must "comport[] with 'traditional notions of fair play and substantial justice.'" Mosseri, 736 F.3d at 1355 (citations omitted). Plaintiffs bear the burden of establishing the first two prongs, and if they do, Defendants bear the burden of making "a 'compelling case' that the exercise of jurisdiction would violate traditional notions of fair play and substantial justice." Id. (quoting Diamond Crystal, 593 F.3d at 1267). As the Eleventh Circuit has stated, "the heart of this protection is fair warning": due process requires that a defendant "should reasonably anticipate being haled into court" in the forum state because of that defendant's conduct in and connection with the state. Diamond Crystal, 593 F.3d at 1267 (quoting Burger King Corp. v. Rudzewicz, 471 U.S. 462, 474 (1985)).

*First*, Plaintiffs must show that their claims "arise out of or relate to" Utah Medical's contacts with Georgia. Mosseri, 736 F.3d at 1355. This inquiry focuses on "the direct causal relationship between the defendant, the forum, and the

litigation." Id. at 1355–56 (quoting Fraser v. Smith, 549 F.3d 842, 850 (11th Cir. 2010)). Utah Medical claims that a causal relationship is impossible here because it did not manufacture or sell the specific clips implanted into Plaintiffs. Dkt. No. [33] at 11. Femcare manufactured them, and CooperSurgical sold them. Id. Utah Medical itself only gained distribution rights to the clips in 2019, six years after the last Plaintiff's implantation surgery. Id. Consequently, Utah Medical argues that this timing prevents Plaintiffs from showing a causal connection between Utah Medical's Georgia contacts and Plaintiffs' claims. Id. at 11–13.

The Court, however, finds that Plaintiffs have met this threshold requirement. Plaintiffs reference Utah Medical's ongoing contacts with Georgia through its distribution of Filshie Clips and its marketing of the product as safe and effective in Georgia. Dkt. No. [29] at 14–19. Plaintiffs' claims include negligence, gross negligence, and consumer protection law violations for deceptive conduct relating to the marketing and promotion of Filshie Clips. Dkt. No. [17] ¶¶ 143–82. At least these three claims, if not more, "arise out of or relate to" Utah Medical's Georgia contacts, especially because Utah Medical had contacts with Georgia before Plaintiffs discovered their injuries resulting from the Filshie Clips. Thus, Utah Medical's current contacts are relevant to Plaintiffs' post-2019 treatments, as well as the remaining issues with Plaintiffs' Filshie Clips, and are sufficient to satisfy this first prong.

*Second*, Plaintiffs must show that Utah Medical purposefully availed itself "of the privileges of doing business within the forum" and therefore "should

reasonably anticipate being haled into court in the forum." Mosseri, 736 F.3d at 1357. A showing that the nonresident defendant "deliberately affiliated" itself with the forum is enough to show purposeful availment. Diamond Crystal, 593 F.3d at 1269 (alterations adopted) (quoting Burger King, 471 U.S. at 482). Some examples of such actions by nonresident defendants include "participating in the manufacturing process" and engaging in business transactions in the forum state. Id. at 1268–69.

Again, Plaintiffs have shown sufficient engagement for purposeful availment. Utah Medical itself does not contest the fact that it acquired U.S. distribution rights for Filshie Clips in 2019 or that it advertises and promotes the clips as safe effective, and it implies that it now does business in Georgia. Dkt. No. [33] at 11, 13–14. As a nationwide distributor of a popular medical device, Utah Medical could reasonably anticipate being haled into court in Georgia, where Plaintiffs' claims arose. In Mosseri, the Eleventh Circuit found that hosting an interactive website coupled with selling and distributing goods through that website to consumers in the state constituted purposeful availment. Mosseri, 736 F.3d at 1357–58. With allegations of both Utah Medical's false online advertising and Utah Medical's role in the chain of distribution for Filshie Clips, Plaintiffs have shown that Utah Medical purposefully availed itself of the privileges of doing business in Georgia.

*Third*, Defendants must demonstrate that subjecting them to personal jurisdiction here would undermine fair play and substantial justice. Defendants have not made such a showing. Factors to consider in this analysis include (1) "the

burden on the defendant," (2) "the forum's interest in adjudicating the dispute," (3) "the plaintiff's interest in obtaining convenient and effective relief," and (4) "the judicial system's interest in resolving the dispute." Licciardello v. Lovelady, 544 F.3d 1280, 1284 (11th Cir. 2008) (citing World-Wide Volkswagen Corp. v. Woodson, 444 U.S. 286, 292 (1980)). Utah Medical did not claim that it would suffer any hardship by defending this case in Georgia, and Plaintiffs have a strong interest in obtaining relief in their home state, where Defendant Utah Medical currently does business. Thus, Defendants failed to show how this Court exercising jurisdiction over Utah Medical would "offend 'traditional notions of fair play and substantial justice.'" Int'l Shoe Co. v. Wash., 326 U.S. 310, 316 (1945) (quoting Milliken v. Meyer, 311 U.S. 457, 463 (1940)).

In sum, the Court finds that it may exercise personal jurisdiction over Defendant Utah Medical because of Utah Medical's contacts with the forum state.[3] Utah Medical does not challenge its status as the sole distributor of Filshie Clips in the United States, and it does not dispute Plaintiffs' allegations that it currently does business in Georgia. By advertising Filshie Clips online and sharing information about their purported safety and effectiveness, Utah Medical has purposefully availed itself of the privileges of doing business in Georgia, and these

[3] Plaintiffs alternatively argued that Utah Medical could be subject to this Court's jurisdiction based on an alter ego theory through its relationship with its subsidiary, Defendant Femcare. Dkt. No. [29] at 17–23. Because the Court finds that it can exercise jurisdiction over Utah Medical on its own contacts, the Court need not consider the parties' arguments regarding the alter ego theory of personal jurisdiction for Defendant Utah Medical.

contacts relate to Plaintiffs' claims, which concern misleading promotions about Filshie Clips' safety. Therefore, Utah Medical is subject to this Court's jurisdiction, and Utah Medical's Motion to Dismiss [25] is **DENIED** as to personal jurisdiction.

***3. The Cooper Companies***

In its initial Motion to Dismiss, Defendant Cooper Companies makes the same jurisdictional arguments as Utah Medical. Cooper Companies argues that it is not subject to the Court's personal jurisdiction because it claims that it did not have any contacts with Georgia or the prescribing physicians relating to Filshie Clips at the time relevant to Plaintiffs' claims. Dkt. No. [24] at 8, 13. Like Utah Medical, Defendant Cooper Companies argues that the Court can disregard Georgia's long-arm statute because due process bars the Court from exercising jurisdiction here, but Defendant contends that even looking to the long-arm statute, Plaintiffs still failed to show the necessary contacts with Georgia. Id. at 11. Further, Defendant Cooper Companies alleges that even if it now has any contacts with Georgia, there is no nexus between its contacts and this litigation because they did not have sufficient contacts with the state for Plaintiffs' claims to "arise out of" those contacts. Id. at 13–14.

In response, Plaintiffs argue that Cooper Companies is the alter ego of CooperSurgical; they do not allege that Cooper Companies would be subject to personal jurisdiction on its own contacts. Plaintiffs' primary argument is that Defendants Cooper Companies and CooperSurgical share directors, officers, and legal counsel between their parent and subsidiary companies. Dkt. No. [28] at 15–

19. Plaintiffs also reference a July 2020 press release from Cooper Companies naming a new CooperSurgical president and stating that this president would report to Cooper Companies leadership to emphasize the executives' overlapping leadership roles. Id. at 18–19. Defendants contend that shared leadership is a standard business practice, that shared press releases are typical in brand marketing, and that the Court should defer to the corporate form.[4] Dkt. No. [33] at 9. Even if this structure is commonplace, it does indicate some shared control and potentially could support an alter ego theory if accompanied by other significant facts.

Next, Plaintiffs focus on how much control Cooper Companies exercises over CooperSurgical. In particular, they argue that Cooper Companies manages and announces acquisitions to boost CooperSurgical's business, indicating that Cooper Companies retains a high level of control over CooperSurgical. Dkt. No. [28] at 19–21. Plaintiffs allege that announcements regarding CooperSurgical often come from its parent, Cooper Companies, and that both companies share press releases and website content. Id. From these shared press releases, Plaintiffs make four conclusions: (1) Cooper Companies has significant control over CooperSurgical's

[4] Defendants also urge the Court not to consider Plaintiffs' alter ego theory, and Plaintiffs' attached exhibits, because they were not part of Plaintiffs' Complaint, Dkt. No. [33] at 5, but as Cooper Companies notes in its Motions to Dismiss, the Court may consider information outside the pleadings in personal jurisdiction analyses. Dkt. No. [24] at 12; see also Stubbs v. Wyndham Nassau Resort & Crystal Palace Casino, 447 F.3d 1357, 1360 (11th Cir. 2006) (explaining that the burden shifts back to the plaintiff to produce evidence supporting personal jurisdiction once it is challenged by a defendant).

corporate dealings, especially acquisitions; (2) Cooper Companies leadership is involved in CooperSurgical by announcing and commenting on CooperSurgical's vision, future, and dealings; (3) Cooper Companies leadership does not consider itself separate and distinct, especially because it refers to CooperSurgical employees as part of the "Cooper family"; and (4) CooperSurgical posts Cooper Companies press releases on its own website. Id. at 21. In its reply to Plaintiffs' arguments, Defendants state that Cooper Companies is not CooperSurgical's direct parent company; instead, Cooper Companies owns Cooper Medical, Inc., which is CooperSurgical's parent. Dkt. No. [33] at 9–10. Thus, Cooper Companies is a step removed from CooperSurgical but still in the same corporate group.

These facts all tend to show a close relationship between Cooper Companies and CooperSurgical, but this evidence alone is not sufficient to support an alter ego theory of jurisdiction. Plaintiffs alternatively requested limited jurisdictional discovery on the issue of personal jurisdiction over Defendant Cooper Companies. Dkt. No. [28] at 22–24. Defendants argue that granting limited discovery is improper because Plaintiffs did not articulate their alter ego theory in their Complaint, could obtain financial information from public sources, and did not file an independent motion for discovery; but the only binding authority that Defendants cite does not compel this result. Dkt. No. [33] at 10; see United Techs. Corp. v. Mazer, 556 F.3d 1260, 1280–81 (11th Cir. 2009) (finding that the district court did not err in failing to grant discovery on an abuse of discretion standard). Although, like the plaintiff in Mazer, Plaintiffs did not formally move for discovery

outside of their filings, the Court finds that Plaintiffs' requests for discovery are appropriate in this case.

"[F]ederal courts have the power to order, at their discretion, the discovery of facts necessary to ascertain their competency to entertain the merits." Eaton v. Dorchester Dev., Inc., 692 F.2d 727, 729 (11th Cir. 1982). Jurisdictional discovery requests "should not serve as fishing expeditions" and "are appropriate only when 'a party demonstrates that it can supplement its jurisdictional allegations through discovery.'" Wolf v. Celebrity Cruises, Inc., 683 F. App'x 786, 792 (11th Cir. 2017) (per curiam) (quoting Trintec Indus., Inc. v. Pedre Promotional Prod., Inc., 395 F.3d 1275, 1283 (Fed. Cir. 2005)). Based on the facts provided, the Court finds that Plaintiffs have made a colorable claim of jurisdiction over Defendant Cooper Companies and that limited discovery will allow the Court to "ascertain the truth of the allegations or facts underlying the assertion of personal jurisdiction." Atlantis Hydroponics, Inc., v. Int'l Growers Supply, Inc., 915 F. Supp. 2d 1365, 1380 (N.D. Ga. 2013). Accordingly, the Court **GRANTS** Plaintiffs' request for limited jurisdictional discovery regarding Defendant Cooper Companies. Thus, Defendant's Motion to Dismiss [24] for lack of personal jurisdiction over Cooper Companies is **DENIED** without prejudice.

***4. Femcare, Ltd.***

Finally, Defendant Femcare, a U.K. company, asserts that it is not subject to this Court's jurisdiction because it has not done business in, nor made other sufficient minimum contacts with, Georgia or any physicians using Filshie Clips in

the state. Dkt. No. [55] at 8–9. Femcare argues that Plaintiffs cannot satisfy Georgia's long-arm statute because they cannot show that Femcare "transacts any business" in Georgia based only on their allegations that Femcare placed Filshie Clips into the "stream of commerce." Id. at 17. Femcare also recognizes that another provision of the Georgia long-arm statute may be relevant. Id. at 17. That provision provides jurisdiction over a defendant that "[c]ommits a tortious injury in this state caused by an act or omission outside this state if the tort-feasor regularly does or solicits business, or engages in any other persistent course of conduct, or derives substantial revenue from goods used or consumed or services rendered in this state." O.C.G.A. § 9-10-91(3). Femcare argues that this provision should not apply because Plaintiffs have not specifically pled facts to support such a finding. Dkt. No. [55] at 17–18. Instead, Femcare disputes that it has done any business in Georgia through affidavit evidence. Id. at 18; Dkt. No. [55-1].

Additionally, Femcare contends that exercising jurisdiction over it would violate due process because Femcare does not have sufficient minimum contacts with Georgia and because maintaining the case in Georgia would violate traditional notions of fair play and substantial justice. Dkt. No. [55] at 9. Femcare relies heavily on the U.S. Supreme Court's decision in J. McIntyre Machinery, Ltd. v. Nicastro, 564 U.S. 873 (2011), in which a plurality of the Court determined that a foreign company simply placing a product in a nationwide "stream of commerce" with the understanding that the product may be purchased in a certain state does not create the necessary minimum contacts with any specific forum state. Dkt. No.

[55] at 12–14. Femcare contends that, like the defendant in that case, it did not target Georgia for Filshie Clip business and "does not sell Filshie Clips with the intent that they be used by medical professionals treating patients in the State of Georgia." Dkt. No. [55] at 14; Dkt. No. [55-1] at 2.

In Response, Plaintiffs claim that Femcare has sufficient minimum contacts with the state and that Plaintiffs' cause of action arises out of injuries from Femcare's product, which Femcare manufactured and knowingly had distributed in Georgia. Dkt. No. [56] at 13. Femcare received FDA approval to sell Filshie Clips in the United States and entered distribution agreements to place Filshie Clips into the stream of commerce in the United States. Id. Plaintiffs argue that Femcare retained significant control over and involvement in U.S. distribution through its agreements and remained responsible for meeting FDA requirements governing the product. Id. at 14–17. Plaintiffs dispute Femcare's J. McIntyre Machinery v. Nicastro interpretation and focus on Femcare's role as a worldwide manufacturer with a significant U.S. market, claiming that Femcare should reasonably anticipate being haled into court in Georgia. Id. at 17–23.

Plaintiffs also note that Femcare does not dispute that its Filshie Clips were used in Georgia, that it knew the products were sold in Georgia, that it profited from this consumption in Georgia, and that it was responsible for adhering to applicable FDA guidelines for the clips used in Georgia. Id. at 23. Moreover, Plaintiffs point out that Femcare does not claim that it prevented its products from reaching Georgia. Id. According to Plaintiffs, Femcare's theory of personal

jurisdiction would permit it to sell defective products in every U.S. state but shield itself from liability by refusing to target any specific state. Id. at 23–24.

Plaintiffs alternatively request that the Court grant limited discovery as to jurisdiction over Femcare because it cannot otherwise access information regarding the full extent of Femcare's potential contacts with Georgia. Dkt. No. [56] at 24 n.20. Based on the facts presented, Plaintiffs have shown that personal jurisdiction over Femcare may be proper, depending on additional facts available only from Femcare itself. Wolf, 638 F. App'x at 792. Accordingly, the Court **GRANTS** Plaintiffs' request for limited jurisdictional discovery regarding Defendant Femcare. Thus, Defendant Femcare's Motion to Dismiss [55] for lack of personal jurisdiction is **DENIED** without prejudice.

**B. Venue**

Next, Defendants Cooper Companies, Utah Medical, and Femcare argue that venue is improper in this Court. As a preliminary matter, Defendants Cooper Companies and Utah Medical contend that Plaintiffs abandoned their venue arguments by not addressing venue in their responses, rendering Defendants' Motions to Dismiss on these grounds unopposed. Dkt. No. [33] at 15. Defendants are incorrect. Plaintiffs replied to Defendants' venue arguments by contending that if the Court finds proper jurisdiction, it should also find proper venue because a substantial part of the events giving rise to the claim occurred here. Dkt. No. [28]

at 24 n.10; Dkt. No. [29] at 24 n.8. Therefore, the Court considers Defendants' venue arguments in full.

The federal venue statute provides, in relevant part, that venue is proper in a district where (1) "any defendant resides, if all defendants are residents of the State in which the district is located," (2) in a district where "a substantial part of the events" that give "rise to the claim occurred," or (3) in "any judicial district in which any defendant is subject to the court's personal jurisdiction with respect to such action," if there is no other available district under 28 U.S.C. § 1391(b)(1)–(2). 28 U.S.C. § 1391(b). Defendants carry a "heavy burden" when opposing venue because a plaintiff's choice of forum is entitled to both deference and "a presumption in favor of" that venue. Wilson v. Island Seas Invs., Ltd., 590 F.3d 1264, 1269 (11th Cir. 2009) (citations omitted).

Here, (b)(1) does not apply because Defendants are not residents of Georgia. Instead, Plaintiffs contend that a substantial part of the relevant events occurred in the Northern District of Georgia and that Defendants do business in Georgia related to Plaintiffs' claims, making venue proper under 28 U.S.C. § 1391(b)(2). Dkt. No. [17] ¶ 16. Defendants claim that none of their acts or omissions related to the claims occurred in this District. Dkt. No. [24] at 14–17; Dkt. No. [25] at 14–16; Dkt. No. [55] at 20. But as explained above, Utah Medical's contacts with Georgia are related to Plaintiffs' claims, which Plaintiffs contend arose here. Further, Plaintiffs all reside in this District, meaning that at least significant portions of their on-going injuries and treatment—which are vital to their claims—have

occurred here. Dkt. No. [17] ¶ 4. Plaintiffs assert claims under Georgia state law, and no party has indicated another forum where venue may be more appropriate based on a substantial portion of the related events taking place in that district. Therefore, Plaintiffs have made a sufficient showing that venue is proper in this District. Therefore, the Court finds that venue is proper under 28 U.S.C. § 1391(b)(2) and need not address the parties' arguments regarding § 1391(b)(3) or 18 U.S.C. § 1965. Defendants' Motions to Dismiss for improper venue are **DENIED**.

### C. Parent Company Liability

Apart from Plaintiffs' alter ego theory for personal jurisdiction, Defendants Cooper Companies and Utah Medical make conclusory arguments that they are not directly liable, and cannot be found indirectly liable, for their subsidiaries' conduct relating to Plaintiffs' claims. Dkt. No. [24] at 18–19; Dkt. No. [25] at 18–19. In their Responses to Defendants' Motions to Dismiss, Plaintiffs conflate this liability argument with their alter ego theory of personal jurisdiction. Dkt. No. [28] at 15–22; Dkt. No. [29] at 19–23. In any event, Plaintiffs claim that these Defendants are both directly and indirectly liable for Plaintiffs' injuries. As to whether Plaintiffs will have sufficient evidence to support these claims, such a finding is premature. Because there is no determination of liability at the motion to dismiss stage, the Court will not address this issue further at this time. The Court has determined that is has personal jurisdiction over Utah Medical and will determine jurisdiction over Cooper Companies after limited discovery. Whether either of these companies

is liable for its subsidiary's conduct is a question of the merits of Plaintiffs' case, to be determined at a later stage in the litigation and after discovery. At this stage, the Court finds Plaintiffs' pleadings sufficient. Thus, Defendants Cooper Companies and Utah Medical's Motions to Dismiss on parent company liability grounds are **DENIED**.

**D. Preemption**

Turning now to Defendants' substantive arguments, the Court begins with Defendants' contention that federal law preempts Plaintiffs' claims, all of which rest on state law. Specifically, Defendants argue that because Filshie Clips are a Class III medical device regulated by the FDA, federal regulations govern the manufacturers, who cannot also be held liable under state law. Dkt. No. [24] at 20–26; Dkt. No. [25] at 19–26; Dkt. No. [26] at 7–13; Dkt. No. [55] at 21–28. Plaintiffs, however, contend that federal law does not block their claims because they rest on violations of those federal regulations, not on separate duties. Dkt. No. [27] at 6–14; Dkt. No. [28] at 4–12; Dkt. No. [29] at 4–12; Dkt. No. [56] at 5–11. Examination of this issue requires several steps. This section thus proceeds as follows: (1) a description of the federal regulatory scheme that encompasses Filshie Clips, (2) a discussion of the federal statutory and case law on this preemption issue, (3) analysis of Defendants' express preemption arguments, and (4) a brief evaluation of the parties' implied preemption arguments.

### *1. Medical Device Amendments & Premarket Approval*

Congress passed the Medical Device Amendments of 1976 ("MDA") to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360c *et seq*., to create a uniform regulatory scheme for medical devices. The MDA fashioned three distinct classes of devices based on their potential risks. Riegel v. Medtronic, Inc., 552 U.S. 312, 316–17 (2008). Class III holds the most dangerous devices, characterized as such because the controls used for Classes I and II are not sufficient to ensure these devices' safety. 21 U.S.C. § 360c(a)(1)(C). Filshie Clips are a Class III medical device. Dkt. No. [17] ¶ 25.

To gain Class III status, Filshie Clips passed the FDA's "rigorous" premarket approval ("PMA") testing. Dkt. No. [17] ¶ 41; 21 U.S.C. § 360e; Riegel, 552 U.S. at 317–18. PMA requires applicants to submit detailed reports of studies and investigations regarding the device's safety and efficacy; full descriptions of the device's components, methods, packaging, and more; and proposed labeling, among other things. Riegel, 552 U.S. at 318 (citing 21 U.S.C. § 360e(c)(1)). Based on these materials, the FDA must determine whether there is "reasonable assurance" of the device's safety and effectiveness. 21 U.S.C. § 360e(d). To do so, the FDA may consult outside experts, request additional data, and conduct other reviews in weighing the health benefits against the risks of injury and illness presented by the device. Riegel, 552 U.S. at 318; 21 U.S.C. § 360c(a)(2)(C).

If, based on this evidence, the FDA decides to grant PMA, "the MDA forbids the manufacturer to make, without FDA permission, changes in design

specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." Riegel, 552 U.S. at 319. Devices with PMA are also subject to ongoing reporting requirements: manufacturers must "inform the FDA of new clinical investigations or scientific studies concerning the device which the applicant knows of or reasonably should know of," and they must "report incidents in which the device may have caused or contributed to death or serious injury[] or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred." Id. (citations omitted). The FDA has authority to withdraw PMA based on new or existing information, and it "must withdraw approval if it determines that a device is unsafe or ineffective under the conditions in its labeling." Id. at 319–20. Thus, manufacturers granted PMA for their devices must comply with specific regulations promulgated by the FDA, as necessary to sustain approval.

***2. Preemption Law***

The MDA was spurred in part by states placing varied requirements on manufacturers; Congress sought to centralize medical device regulations within the federal government through these amendments. Id. at 315–16. To ensure nationwide standardization, Congress included an *express* preemption provision in the MDA:

> Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

The Supreme Court discussed the MDA's express preemption provision at length in two cases: Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996), and Riegel v. Medtronic, Inc., 552 U.S. 312 (2008). First, in Lohr, the Supreme Court explained that the MDA protects manufacturers from liability when they comply with federal law, but the Amendments do not foreclose state claims based on breaches of common law duties that parallel existing federal requirements. Lohr, 518 U.S. at 487–88 (plurality opinion); id. at 494–95 (majority opinion); see also Mink v. Smith & Nephew, Inc., 860 F.3d 1319, 1328–29 (11th Cir. 2017) (discussing Lohr). The Lohr plurality also emphasized the risk of interpreting the MDA preemption provision too broadly, describing the defendant's preferred construction as having "the perverse effect of granting complete immunity from design defect liability to an entire industry that" Congress sought to regulate more stringently through the MDA. Lohr, 518 U.S. at 487 (plurality opinion); see also id. (finding it "difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct" (quoting Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 251 (1984))).

Then, in Riegel, the Supreme Court set forth a two-part preemption test—which all parties agree governs the Court's analysis here. Under this doctrine, the Court must determine (1) whether federal government requirements apply to

Filshie Clips and (2) whether Plaintiffs' state law claims relate to the clips' safety and effectiveness and rest on requirements that are "different from, or in addition to," the federal requirements. Riegel, 552 U.S. at 321–22 (quoting 21 U.S.C. § 360k(a)(1)). No one disputes that the first prong is met. By virtue of their PMA, Filshie Clips are subject to federal requirements. Dkt. No. [17] ¶¶ 30, 41; Riegel, 552 U.S. at 322–23. As to the second prong, Defendants argue that Plaintiffs' claims concern the safety and effectiveness of Filshie Clips because they pertain to design, construction, and other facets of the device specifically regulated by the FDA. Dkt. No. [24] at 20; Dkt. No. [25] at 20; Dkt. No. [26] at 7; Dkt. No. [55] at 22. Plaintiffs do not contradict that assertion, and the Court agrees that Plaintiffs' claims concern safety and effectiveness. Thus, the Court must only determine whether Plaintiffs' common law claims impose *additional or different requirements* relating to Filshie Clips' safety and effectiveness.

In 2001, the Supreme Court found that the MDA can also serve as the basis for *implied* preemption of certain claims in Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001). In particular, the Court determined that "state-law fraud-on-the-FDA claims conflict with" federal law. Buckman, 531 U.S. at 347–48. The Court reasoned that allowing state claims in this vein would hamper the FDA's ability to punish and deter fraud perpetrated against it, requiring implied preemption to block those claims. Id.

Since Riegel, the Eleventh Circuit has consistently held that federal law does not preempt state law claims of the type that Plaintiffs allege here. E.g., Mink, 860

F.3d 1319; Godelia v. Doe, 881 F.3d 1309 (11th Cir. 2018); Jacob v. Mentor Worldwide, LLC, 40 F.4th 1329 (11th Cir. 2022). But see Wolicki-Gables v. Arrow Int'l, Inc., 634 F.3d 1296 (11th Cir. 2011) (finding that the MDA preempted certain state law claims in consideration of summary judgment). In each of the cases finding that the state claims were not preempted, the Eleventh Circuit determined that the plaintiffs' claims imposed requirements that were "parallel" or "genuinely equivalent" to the federal requirements, not different or additional ones. Mink, 860 F.3d at 1325–27 (quoting Wolicki-Gables, 634 F.3d at 1300); see also id. at 1330 ("[Defendant]'s violation of a federal requirement also caused the violation of a state-law duty."); Godelia, 881 F.3d at 1319 (finding that allegations regarding strict liability and negligence were sufficient to avoid express preemption because they referenced violations of specific federal regulations). Thus, the MDA does not expressly preempt state law claims that rest on alleged violations of existing federal requirements.

In Mink, the plaintiff alleged negligence and strict liability, among other claims, under Florida common law for injuries caused by the defendant's hip replacement system. Mink, 860 F.3d at 1323. The district court granted the defendant's motion to dismiss on both Florida law and implied and express preemption grounds. Id. at 1324. The Eleventh Circuit reversed in part, finding that the plaintiff's negligence and strict liability claims should both survive

dismissal because they were cognizable under state law[5] and not preempted by federal law. Id. at 1333–34. Relying on Supreme Court precedent, the court explained,

> To avoid having his claims preempted, a plaintiff must carefully plead a claim that implicates the safety or effectiveness of a federally[]regulated medical device. Express preemption will bar state-law claims that impose on the medical device a requirement different from or additional to federal requirements. And implied preemption prohibits state-law claims that seek to privately enforce duties owed to the FDA.

Id. at 1327 (citations omitted).

Thus, MDA preemption leaves "a 'narrow gap'" for pleadings to avoid preemption: "a plaintiff has to sue for conduct that violates a federal requirement (avoiding express preemption), but cannot sue only because the conduct violated that federal requirement (avoiding implied preemption)." Id. (citations omitted). In Mink, the plaintiff's negligence and strict liability allegations regarding a manufacturing defect threaded this needle because the claims were "expressly limit[ed]" to "those that '[we]re parallel to and not different from or in addition to the requirements of federal law.'" Id. at 1329. Importantly, the Eleventh Circuit noted that "the Florida common law duty to use due care in manufacturing a

[5] Defendants do not challenge the adequacy of Plaintiffs' pleadings on state law grounds—except for in their learned intermediary doctrine argument, which is discussed further below. Therefore, the Court need not complete the threshold state law analysis that the Eleventh Circuit examined in Mink and Godelia. Mink, 860 F.3d at 1329–31; Godelia, 881 F.3d at 1318–19, 21–22. Instead, the Court considers Defendants' preemption arguments as presented, accepting Plaintiffs' claims as adequately pled under Georgia law.

medical device" is a duty owed to individuals that runs parallel to the federal requirement. Id. at 1330. Therefore, the defendant's "violation of a federal requirement also caused the violation of a state-law duty," so the plaintiff's claims were not preempted. Id.

***3. Express Preemption***

Defendants have not persuaded the Court that a different outcome should follow here. Both Florida and Georgia law permit negligence and strict liability claims against manufacturers, which rest on common law duties owed to individuals. Id. at 1331; Maynard v. Snapchat, Inc., 870 S.E.2d 739, 744–46 (Ga. 2022). Like the plaintiff in Mink, Plaintiffs here have alleged violations of these state common law duties owed to Plaintiffs. Mink, 860 F.3d at 1334. For example, Plaintiffs claim that Defendants had a duty to prevent manufacturing defects, to warn of the risk of harm, and to exercise ordinary care, each of which Plaintiffs connect to a parallel federal requirement. E.g., Dkt. No. [17] ¶¶ 115, 123, 145, 154. Furthermore, in both cases, the plaintiffs acknowledged the risk of preemption and explicitly limited their pleadings to parallel violations of federal law. Mink, 860 F.3d at 1329; e.g., Dkt. No. [17] ¶¶ 23–36. Thus, Eleventh Circuit precedent indicates that the MDA does not expressly preempt all state law tort claims for injuries suffered from dangerous medical devices, like Plaintiffs' injuries here.

Next, Defendants argue that allowing Plaintiffs' claims to proceed would permit a jury to contradict the FDA's decisions about Filshie Clips' warnings, design, and manufacturing. Dkt. No. [24] at 23 n.26, 25–26; Dkt. No. [25] at 22

n.22, 25–26; Dkt. No. [26] at 9 n.12, 12–13; Dkt. No. [55] at 24 n.22, 27–28. They contend that doing so would risk displacing the FDA's expert judgments for decisions of judges and juries, effectively applying a "different standard" to medical device manufacturers. Dkt. No. [24] at 25–26; Dkt. No. [25] at 25–26; Dkt. No. [26] at 12–13; Dkt. No. [55] at 27–28. The Riegel Court, which Defendants rely on, did discuss how state tort juries could be disruptive to the FDA's standardized regulatory scheme. Riegel, 552 U.S. at 325 (finding that state tort law requiring devices "to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme" and noting that juries may not weigh costs and benefits of devices in the same way as official regulators). There, however, the plaintiffs had not argued that their lawsuit raised parallel claims at the district court—which construed the plaintiffs' claims as asserting state law violations despite the defendant's compliance with federal law—so the Supreme Court declined to consider that question in the first instance. Id. at 330. Thus, as the Eleventh Circuit has explained, the Riegel holding "was limited to violations of state tort law 'notwithstanding compliance with the relevant federal requirements.'" Mink, 860 F.3d at 1330 (quoting Riegel, 552 U.S. at 330). Accordingly, this holding leaves open claims premised on federal violations that enforce state law duties.

Plaintiffs' claims more closely mirror those in Mink than those preempted in Riegel because they seek to hold Defendants liable for violations of existing federal requirements. In Mink, the Eleventh Circuit explained that such parallel state

claims, even those with additional *elements*, do not necessarily impose additional *requirements* on manufacturers. Id. at 1330–31. Indeed, the Mink court reasoned that the state law elements for negligence and strict liability there imposed a narrower (not a broader) responsibility on the manufacturers than federal law did; thus, the state law claims did not impose "different or additional" requirements. Id. (citing Lohr, 518 U.S. at 495 (majority opinion)). Similarly, Plaintiffs' claims here would simply provide them with a damages remedy for existing violations of federal regulations through this state common law avenue because of the state law duties owed to Plaintiffs. Thus, like in Mink, "this claim is precisely the type the Supreme Court has told us survives express preemption." Id. at 1331 (citing Riegel, 552 U.S. at 330). Moreover, as Plaintiffs point out, to find otherwise would be to impermissibly grant broad immunity from state law liability to all medical device manufacturers—the "perverse effect" that the Supreme Court warned against in Lohr. Id. (quoting Lohr, 518 U.S. at 487 (plurality opinion)). Therefore, the Court finds that Plaintiffs' claims are not expressly preempted.

Defendants also contend that Plaintiffs cannot avoid preemption simply by purporting to assert parallel claims and that Plaintiffs claims are not sufficiently specific to avoid preemption. Dkt. No. [24] at 26 n.31 Dkt. No. [25] at 26 n.27; Dkt. No. [26] at 13 n.17; Dkt. No. [33] at 2; Dkt. No. [55] at 28 n.28. Defendants cite Wolicki-Gables, in which the Eleventh Circuit stated that a plaintiff "cannot simply incant the magic words" that a defendant violated FDA regulations. Wolicki-Gables, 634 F.3d at 1301 (quoting In re Medtronic Inc., 592 F. Supp. 2d 1147, 1158

(D. Minn. 2009)). In that decision, the court continued, "[p]arallel claims must be specifically stated in the initial pleadings" by pointing to specific PMA requirements that a defendant violated. Wolicki-Gables, 634 F.3d at 1301. But after Wolicki-Gables, the Eleventh Circuit recognized that a plaintiff cannot always access all of the FDA's specific regulatory requirements for a device without discovery. Godelia, 881 F.3d at 1320. Here, Plaintiffs specifically allege that Defendants violated FDA requirements regarding their ongoing duty to report to the FDA, Dkt. No. [17] ¶ 102; their duty of truthfulness to the FDA and the obligation to receive FDA approval for any changes to the device, e.g., id. ¶¶ 115, 123, 138, 154, 164; and their failure to comply with FDA manufacturing regulations, id. ¶ 153(i). These allegations are sufficiently specific to avoid preemption, especially at this stage of litigation and without the benefit of discovery.

Last, Defendants also present decisions from other courts that have found state law claims expressly preempted by the FDA, but the only binding authority that Defendants cite to support that proposition is the Eleventh Circuit's decision in Wolicki-Gables.[6] Dkt. No. [24] at 24–25; Dkt. No. [25] at 24–25; Dkt. No. [26]

[6] In addition to cases from other jurisdictions, Defendants cite four Eleventh Circuit district court cases, but they all predate the Eleventh Circuit's decisions in Mink, Godelia, and Jacob. Dkt. No. [24] at 24 n.29; Dkt. No. [25] at 24 n.25; Dkt. No. [26] at 11 n.15; Dkt. No. [55] at 26 n.25. Defendants do also point to one recent district court case. Dkt. No. [42-1]. But in that case, rather than dismissing the plaintiffs' claims on preemption grounds, the court granted the parties a chance to replead their allegations to avoid preemption. Froman v. Coopersurgical, Inc., 2:22-cv-00110-AKK, 2022 WL 2657117, at *7 (N.D. Ala. July 8, 2022). Thus, the

at 11–12; Dkt. No. [55] at 26–27. Based on more recent Eleventh Circuit case law, Wolicki-Gables does not require a finding of preemption here, though. In addition to the reasons provided in the preceding paragraph, Wolicki-Gables is also readily distinguishable from this case based on Jacob, a 2022 Eleventh Circuit decision. In Jacob v. Mentor Worldwide, LLC, the Eleventh Circuit distinguished Wolicki-Gables from its other preemption precedent in part because Wolicki-Gables was at the summary judgment, rather than dismissal, stage, giving those Plaintiffs the benefit of discovery. Jacob, 40 F.4th at 1338. Here, like in Jacob, the litigation is only at the pleading stage. Further, in Wolicki-Gables, the plaintiffs did not plead specific federal violations; instead, they alleged only a failure to act "reasonably" with regards to manufacturing and designing the device at issue. Id. (quoting Wolicki-Gables, 634 F.3d at 1301). As explained above, Plaintiffs' claims rest directly on Defendants' alleged violations of FDA requirements, and Plaintiffs carefully pled their Complaint to avoid express preemption. Thus, Defendants' reliance on Wolicki-Gables is not controlling, and Defendants have not met their burden to show that Plaintiffs' claims are expressly preempted.

***4. Implied Preemption***

Finally, Defendants did not address implied preemption in their Motions to Dismiss. E.g., Dkt. No. [24] at 22 ("Federal Law Expressly Preempts State-Law Claims Concerning Class III Devices Approved through the PMA Process."); Dkt.

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Court is not persuaded that dismissal on preemption grounds is appropriate based on Defendants' arguments from case law.

No. [25] at 22 (same); Dkt. No. [26] at 9 (same); Dkt. No. [55] at 24 (same). In their Joint Reply in Support of their Motions to Dismiss, Defendants Cooper Companies, Utah Medical, and CooperSurgical allude to implied preemption by quoting Mink's discussion of the topic.[7] Dkt. No. [33] at 2–3. Plaintiffs then filed a Sur-Reply to argue that this implied preemption argument was untimely and should not be considered. Dkt. No. [36]. A similar situation followed with Femcare's Motion to Dismiss, filed six months after the other Defendants faced this issue. Dkt. No. [55]. Like the other Defendants, Femcare did not raise an implied preemption argument until its Reply Brief. Dkt. No. [59]. The Court permitted Plaintiffs to file a Sur-Reply in which they again argued that the issue should not be considered because it was not raised in the initial motion. Dkt. No. [62].

Although Plaintiffs did argue that even if the Court considered Defendants' implied preemption arguments, they would fail on the merits in their Sur-Replies, the Court nonetheless declines to consider this argument because of Defendants' failures to address implied preemption in their initial motions. As a general rule, parties may not raise new issues for the first time in reply. See, e.g., United States v. Ga. Dep't of Nat. Res., 897 F. Supp. 1464, 1471 (N.D. Ga. 1995); see also In re

[7] Defendants also mention for the first time in their Joint Reply that any claims alleging missing information in the warnings and labels accompanying Filshie Clips are preempted under Riegel because they call for additional or different requirements, without further elaboration. Dkt. No. [33] at 3. Without more, the Court is not persuaded by this contention at this stage.

Egidi, 571 F.3d 1156, 1163 (11th Cir. 2009) ("Arguments not properly presented in a party's initial brief or raised for the first time in the reply brief are deemed waived."). Here, Defendants Utah Medical, Cooper Companies, and Femcare did not substantially argue implied preemption until their Response to Plaintiffs' Sur-Reply, and even then, they did not indicate how controlling authority would require a finding of implied preemption for any specific counts brought in Plaintiffs' case. Dkt. No. [39]. Femcare, on the other hand, used its Reply to focus primarily on implied, rather than express, preemption, Dkt. No. [39], and contends that Plaintiffs should have been "on notice with respect to Femcare's implied preemption arguments" because of mere citations to cases involving implied preemption in prior filings, Dkt. No. [65] at 2 n.1. Such "notice" is far from sufficient for Defendants to carry their burden on implied preemption in their Motions to Dismiss. Thus, the Court declines to consider Defendants' implied preemption arguments, each raised for the first time after their initial Motions to Dismiss.

In short, Defendants' preemption arguments must fail. The Eleventh Circuit has consistently held that the MDA does not preempt state tort claims like Plaintiffs', especially at the pre-discovery dismissal stage. Thus, the Court finds that Plaintiffs' pleadings are sufficient to survive Defendants' Motions to Dismiss. Therefore, Defendants' Motions to Dismiss on preemption grounds are **DENIED**.

### E. Learned Intermediary Doctrine

Next, Defendants argue that Plaintiffs' failure to warn claims must be dismissed because of the learned intermediary doctrine. Dkt. No. [24] at 28–31; Dkt. No. [25] at 28–30; Dkt. No. [26] at 15–18; Dkt. No. [55] at 28. Plaintiffs respond that the doctrine does not apply at the motion to dismiss stage; instead, they contend that the Court should only consider whether Plaintiffs adequately pled their failure to warn claims. Dkt. No. [27] at 14–16; Dkt. No. [28] at 24–26; Dkt. No. [29] at 24–26; Dkt. No. [56] at 25. The Court agrees with Plaintiffs.

The learned intermediary doctrine provides that manufacturers have a duty to warn a patient's doctor of the dangers involved with their medical products, but they do not have a duty to warn patients directly. McCombs v. Synthes (U.S.A.), 587 S.E.2d 594, 595 (Ga. 2003). This doctrine acts as an exception to the default rule that manufacturers must warn end users of known risks or dangers. Meyerhoff v. Enhancement, Med., LLC, No. 2:15-CV-00078-RWS, 2016 WL 4238643, at *4 (N.D. Ga. Feb. 10, 2016). The rationale is that physicians are the professionals in the best position to understand medical risks and patients' needs. McCombs, 587 S.E.2d at 595; see also Ellis v. C.R. Bard, Inc., 311 F.3d 1272, 1280–81 (11th Cir. 2002) (collecting cases). The warning to prescribing physicians must be "adequate or reasonable under the circumstances of the case." McCombs, 587 S.E.2d at 595.

Here, Plaintiffs allege that Defendants had a duty to warn "Plaintiffs, Plaintiffs' physicians, and/or the medical community" of the risks of Filshie Clip migration and that Defendants failed to adequately warn Plaintiffs and their

healthcare providers of these risks. Dkt. No. [17] ¶¶ 124–25. Although the learned intermediary doctrine may shield Defendants from liability for failure to warn Plaintiffs directly, Plaintiffs adequately stated a claim for failure to warn their physicians.[8] Meyerhoff, 2016 WL 4238643, at *4 (rejecting the defendant's motion to dismiss on learned intermediary doctrine grounds because the plaintiff sufficiently pled a failure to warn claim). The Court does not decide whether the learned intermediary doctrine will ultimately apply in this case. The Court only finds that Plaintiffs' failure to warn (Count 3) allegations are adequate to survive Defendants' Motions to Dismiss on these grounds. Defendants' Motions to Dismiss are **DENIED** as to the learned intermediary doctrine.

**F. Statute of Repose**

Finally, Defendants' most straightforward argument is that a ten-year statute of repose barred Plaintiff Smith's strict liability claim (Count 4) because her Filshie Clip surgery occurred in 2011, over ten years before Plaintiffs filed their Complaint. Dkt. No. [24] at 26–28; Dkt. No. [25] at 26–28; Dkt. No. [26] at 13–15; Dkt. No. [55] at 28. Plaintiffs concede that the statute of repose bars Smith's strict liability claims, but they maintain Smith's other claims and the other Plaintiffs'

[8] Defendants also argue that Plaintiffs cannot state a claim for failure to warn Plaintiffs themselves because such a claim does not exist under Georgia law. Dkt. No. [24] at 29; Dkt. No. [25] at 28–29; Dkt. No. [26] at 16; Dkt. No. [33] at 14; Dkt. No. [55] at 28. Because the Court does not assess the learned intermediary doctrine further at this stage, the Court will not separate Plaintiffs' Count 3 into distinct claims for failure to warn *Plaintiffs* and failure to warn *Plaintiffs' physicians* here either. Plaintiffs alleged sufficient facts to sustain their failure to warn claim.

strict liability claims. Dkt. No. [27] at 18 n.5; Dkt. No. [28] at 26 n.12; Dkt. No. [29] at 27 n.10; Dkt. No. [56] at 25. Because this matter is not contested, Plaintiff Smith's strict liability claims against all Defendants are **DISMISSED**. Defendants' Motions to Dismiss Plaintiff Smith's strict liability claims on statute of repose grounds are **GRANTED**.

## IV. CONCLUSION

In accordance with the foregoing, Defendants' Motions to Dismiss [24, 25, 26, 55] are **GRANTED IN PART** and **DENIED IN PART**. Plaintiff Kimyania Smith's strict liability claims against all Defendants are **DISMISSED**. Thus, Defendants' Motions to Dismiss [24, 25, 26, 55] are **GRANTED** only as to Plaintiff Kimyania Smith's strict liability claims being barred by the statute of repose. Defendants Utah Medical and CooperSurgical's Motions to Dismiss [25, 26] are otherwise **DENIED**.

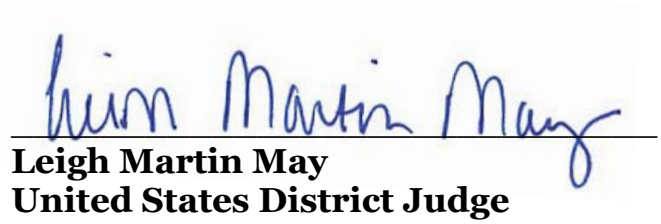
The Cooper Companies Motion to Dismiss [24] is **DENIED** as to its challenges regarding venue, parent company liability, preemption, and the learned intermediary doctrine. Plaintiffs' request for limited jurisdictional discovery as to Defendant Cooper Companies, [28] at 22, is **GRANTED**. Accordingly, the Cooper Companies Motion to Dismiss regarding personal jurisdiction is **DENIED** without prejudice as premature. Cooper Companies may again contest personal jurisdiction at the conclusion of the limited discovery period.

Defendant Femcare's Motion to Dismiss [55] is **DENIED** as to its challenges regarding venue, preemption, and the learned intermediary doctrine. Plaintiffs'

request for limited jurisdictional discovery as to Defendant Femcare, [56] at 24 n.20, is **GRANTED**. Accordingly, Femcare's Motion to Dismiss regarding personal jurisdiction is **DENIED** without prejudice as premature. Femcare may again contest personal jurisdiction at the conclusion of the limited discovery period.

The parties shall have **two (2) months** from issuance of this Order to complete jurisdictional discovery as to Defendants Cooper Companies and Femcare. Defendants must comply with and respond to discovery requests in a timely manner. In the event of a discovery dispute, the parties are directed to comply with the procedures set forth in this Court's Standing Order. See Dkt. No. [7].

**IT IS SO ORDERED** this 17th day of January, 2023.



**Leigh Martin May**
**United States District Judge**