IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF ALABAMA
SOUTHERN DIVISION

JACKIE DIANNA MACK, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	CASE NO. 1:22-cv-54-RAH
	)	[WO]
COOPERSURGICAL, INC., *et al.*,	)	
	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

Jackie Dianna Mack and Frankie Mack bring this personal injury suit—against The Cooper Companies, Inc. (TCC) and its subsidiary CooperSurgical, Inc. (CooperSurgical); and Utah Medical Products, Inc. (UMP) and its subsidiary Femcare, LTD (Femcare)—concerning Filshie Clips that allegedly caused injury to Mrs. Mack. The Defendants are alleged to have manufactured, marketed, and distributed Filshie Clips, a type of contraceptive device. The Macks plead a variety of state law product liability, negligence, and consumer protection claims. The Defendants have moved to dismiss all claims against them. For the reasons that follow, UMP's and TCC's motions to dismiss are due to be granted to the extent they seek dismissal for lack of personal jurisdiction, and CooperSurgical's and Femcare's motions to dismiss are due to be denied.

I. BACKGROUND

A. The Filshie Clip Device

Filshie Clips are silicone-lined titanium medical devices that are attached to a woman's fallopian tubes during a tubal ligation procedure. The clips work by exerting continuous pressure on the fallopian tubes, eventually blocking them and acting as a form of long-term birth control. The Filshie Clip is designed to remain permanently attached to the fallopian tube at its placement location. Femcare obtained conditional premarket approval from the Food and Drug Administration (FDA) for the manufacturing and commercial distribution of the Filshie Clip within the United States in 1996. The device remains on the market today.

B. Mrs. Mack's Experience with Filshie Clips

In 2017, Mrs. Mack underwent a tubal ligation procedure using Filshie Clips. (Doc. 1 at 12.) According to Mrs. Mack, she received pre-procedure disclosure and consent information related to the generic risks and hazards associated with the ligation procedure itself but her doctors did not mention any risk of Filshie Clip migration and the appurtenant damages that could be caused. (*Id.*)

Within months of her procedure in 2017, Mrs. Mack experienced a variety of adverse symptoms due to Filshie Clip migration. (*Id.*) In August 2020, Mrs. Mack underwent surgery where it was discovered that her Filshie Clips had migrated from their original placement. (*Id.* at 13.) As a result, the clips were removed, as was one

of her fallopian tubes. Mrs. Mack continued to experience problems and therefore underwent a complete hysterectomy. (*Id.*)

C. The Macks' Complaint

According to the Complaint, migration of Mrs. Mack's Filshie Clips was not an anomaly, as it was occurring in over 25% of patients. Despite this high rate, the Defendants neither warned nor adequately informed the Macks nor their healthcare providers of how frequently these migrations actually occurred or the severity and permanency of the potential injuries. The Defendants allegedly failed to provide any warning "even though [they] had received adverse reports and knew or should have known Filshie Clips had a significant propensity to migrate." (*Id.* at 9.) And problematically, Femcare had listed the migration rate at 0.13% in its application for premarket approval even though "the risk of migration was significantly higher [than 0.13%] and continued to increase from year to year." (*Id.* at 10.) Still, the Defendants "failed to address the Filshie Clips' safety issues, even though adverse event reports did or should have alerted them to a product defect causing the device to cause injuries." (*Id.*) The Defendants also allegedly failed to report these adverse events to the FDA and to update their marketing materials to reflect the actual risk of clip migration, and the Defendants allegedly breached their duty to continually monitor and test their product to ensure its safety and to adequately warn consumers of the dangers inherent in the use of Filshie Clips.

The Macks claim that these failures, along with the Defendants' related breaches of various duties imposed on manufacturers and distributors of medical devices, caused Mrs. Mack's injuries. The Macks bring state law claims against the Defendants for: (1) design defect; (2) manufacturing defect; (3) failure to warn; (4) strict liability; (5) negligence; (6) "violation of consumer protection laws"; (7) gross negligence; and (8) punitive damages.

II. STANDARD OF REVIEW

A pleading must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). To satisfy this requirement, plaintiffs need not plead "detailed factual allegations" fully outlining the merits of their case. *Bell Atl. v. Twombly*, 550 U.S. 544, 555 (2007). But to survive a motion to dismiss under Rule 12(b)(6), a complaint "must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal citations omitted).

Additionally, to survive a motion to dismiss for lack of personal jurisdiction, a plaintiff's complaint must "allege sufficient facts to make out a *prima facie* case of jurisdiction." *Posner v. Essex Ins. Co*., 178 F.3d 1209, 1214 (11th Cir. 1999) (per curiam). If the defendant challenges jurisdiction through affidavits, the burden shifts back to the plaintiff to produce evidence supporting jurisdiction. *Id.*

III. DISCUSSION

TCC, Femcare, and UMP move for dismissal on largely identical grounds: improper venue, lack of personal jurisdiction, preemption, and the statute of limitations. For its part, CooperSurgical moves for dismissal on preemption, statute of limitations, and shotgun pleading grounds. The Court first addresses the issue of personal jurisdiction.

A. Personal Jurisdiction

"A federal court sitting in diversity may properly exercise jurisdiction over a defendant only if two requirements are met: (1) the state long-arm statute, and (2) the Due Process Clause of the Fourteenth Amendment." *Id.* Because Alabama's long-arm statute confers jurisdiction to Alabama courts to the extent such jurisdiction is constitutionally permissible, these two requirements collapse into one. *Olivier v. Merritt Dredging Co*., 979 F.2d 827, 830 (11th Cir. 1992). Corporate defendants may be brought into court through either general or specific jurisdiction. *See Daimler AG v. Bauman*, 571 U.S. 117, 122 (2014). 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. *Id.* at 137. The Macks do not claim that general jurisdiction exists here, so the Court will not address it.

Specific personal jurisdiction comports with due process if the "non-resident

defendant ha[s] certain minimum contacts with the forum so that the exercise of jurisdiction does not offend traditional notions of fair play and substantial justice." *Meier ex rel. Meier v. Sun Int'l Hotels, Ltd*., 288 F.3d 1264, 1274 (11th Cir. 2002). To satisfy this requirement, the plaintiff bears the burden of establishing that: "(1) [her] claims 'arise out of or relate to' at least one of the defendant's contacts with the forum; [and] (2) [] the nonresident defendant 'purposefully availed' [itself] of the privilege of conducting activities within the forum state, thus invoking the benefit of the forum state's laws." *Louis Vuitton Malletier, S.A. v. Mosseri*, 736 F.3d 1339, 1355 (11th Cir. 2013) (citation omitted). Stated differently, because "[t]he Constitution prohibits the exercise of personal jurisdiction over a nonresident unless [its] contact with the state is such that [it] has 'fair warning' that [it] may be subject to suit there," the plaintiff must show that the nonresident defendant "'purposefully directed' [its] activities at residents of the forum and the litigation results from alleged injuries that 'arise out of or relate to' those activities." *PVC Windoors, Inc. v. Babbitbay Beach Constr., N.V*., 598 F.3d 802, 811 (11th Cir. 2010) (citations omitted).

1. TCC & UMP

a. Specific Jurisdiction Pleading

The Macks generally allege that the four Defendants "purposefully availed themselves of the privilege of conducting business in the State of Alabama and

established minimum contacts sufficient to confer jurisdiction over these Defendants, and the assumption of jurisdiction over Defendants will not offend traditional notions of fair play and substantial justice and is consistent with constitutional requirements of due process." (Doc. 1 at 3–4.)

Other than this boilerplate language[1] directed against the Defendants broadly, the Macks plead no factual basis for personal jurisdiction over TCC. In fact, the Macks do not mention TCC in any of their factual content and explicitly omit TCC from their listing of the defendants that sold Filshie Clips in Alabama and had a hand in the specific Filshie Clips that caused Mrs. Mack's injuries. (*See* Doc. 1 at 4.) Since "vague and conclusory allegations" about a defendant's contacts with the forum "are insufficient to establish a prima facie case of personal jurisdiction," *Snow v. DirecTV, Inc*., 450 F.3d 1314, 1318 (11th Cir. 2006), the Macks have failed to meet their burden of pleading a basis for personal jurisdiction over TCC.

As for UMP, the Macks allege that CooperSurgical, Femcare, and UMP "sell their products and intend that they be used by medical professionals treating patients in Alabama," and that these three defendants, "singularly and in combination, designed, manufactured, sold and distributed Filshie Clips and related equipment utilized in [Mrs. Mack's] tubal ligations." (Doc. 1 at 4, 7.) These allegations

[1] The Court notes that the Complaint is largely a boilerplate complaint in that it is nearly identical to the complaints filed against these Defendants in other jurisdictions.

successfully shift the burden to UMP to submit affidavits or other evidence contradicting the Macks' stated bases for jurisdiction. *See Stubbs v. Wyndham Nassau Resort & Crystal Palace Casino*, 447 F.3d 1357, 1360 (11th Cir. 2006). UMP has done that through a declaration from its Chairman and CEO who states that UMP "did not develop, manufacture, or market the Filshie Clips allegedly used in . . . [Mrs.] Mack's tubal ligation on February 6, 2016," and indeed "did not sell or market . . . Filshie Clips in Alabama or elsewhere" prior to February 2019. (Doc. 18-1.) The burden then shifts back to the Macks "to produce evidence supporting personal jurisdiction" over UMP. *See Stubbs,* 447 F.3d at 1360.

To meet their burden, the Macks cite to specific language in UMP's declaration, which they construe as admitting a basis for jurisdiction: "in his carefully worded declaration, it appears that [UMP] (1) currently sells, markets, and distributes Filshie Clips in Alabama; and (2) has done so since February 2019." (Doc. 37 at 10–11 (emphases omitted).) Basically, although they do not claim that UMP made the specific clips at issue here, the Macks argue that had UMP adequately warned Alabama consumers about the alleged frequency of migrating Filshie Clips when it began marketing the clips in February 2019, Mrs. Mack and her physicians might have discovered the cause of her pain sooner. (*Id.* at 11–13.) Thus, so the theory goes, "[UMP] purposefully avails itself of the privilege of conducting activities in Alabama by currently marketing, selling, and distributing the Filshie

Clip system in Alabama, the *very same product* that is at issue in this litigation," and therefore "it subjected itself to the personal jurisdiction of this Court." (*Id.* at 11.)

The Macks appear to suggest that when a company begins marketing and distributing a product in a particular forum, it, with nothing more, automatically subjects itself to personal jurisdiction for any lawsuit relating to that same product regardless of *when* the product was manufactured, distributed, and sold or *by whom*. This is so, the Macks maintain, even where the allegedly faulty product that caused the plaintiff's injuries was manufactured, distributed, and, in this case, implanted in the plaintiff, long before the defendant company began doing business in the forum state.

This argument falls short. The Macks provide no legal authority supporting this jurisdictional analysis, and their argument entirely disregards the due process clause's "fair warning requirement," which is only satisfied "if the defendant has purposefully directed his activities at residents of the forum . . . and the litigation results from alleged injuries that *arise out of or relate to those activities.*" *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472–73 (1985) (emphasis added). The Court is thus unconvinced that UMP "should reasonably anticipate being haled into [an Alabama] court" for a medical device that UMP had nothing to do with at the time of the device's manufacturing, marketing, distribution, sale, and implantation. *See id.* at 474. After all, Mrs. Mack's Filshie Clips were implanted over two years before

UMP acquired the distribution rights for the product. Accordingly, the Macks have not shown "a sufficient nexus between [UMP's] contacts [with Alabama] and the litigation" to render the exercise of specific personal jurisdiction over UMP here constitutionally permissible. *See Diamond Crystal Brands, Inc. v. Food Movers Int'l, Inc*., 593 F.3d 1249, 1267 (11th Cir. 2010).[2]

On this issue, the Court notes that it does not sail into uncharted waters. As it concern's personal jurisdiction over TCC and UMP in Alabama, the Northern District of Alabama concluded the same under almost identical facts to those presented here. *See Froman v. Coopersurgical, Inc*., No. 2:22-cv-00110-AKK, 2022 WL 2657117 (N.D. Ala. July 8, 2022). The Court finds the decisions in *Froman*, and in *Watters v. Coopersurgical, Inc*., No. 5:22-CV-223-D, 2023 WL 1982347 (E.D.N.C. Feb. 13, 2023), persuasive on this issue.[3]

b. Alter Ego

The Macks alternatively contend that personal jurisdiction exists over both

[2] To the extent the Macks seek limited discovery on this issue, their request is denied. The Macks did not file a formal motion, and the Court declines to entertain an embedded, fall-back request devoid of details as to how such discovery will aide them. *See United Techs. Corp. v. Mazer*, 556 F.3d 1260, 1280–81 (11th Cir. 2009).

[3] The Macks' reliance upon the decision in *Bulox v. Coopersurgical, Inc*., No. CV-21-2320, 2022 WL 2132680 (S.D. Tex. June 14, 2022), is not persuasive because UMP and TCC failed to argue in their initial motion to dismiss that UMP and TCC did not operate in Texas during the time of plaintiffs' surgery. Unlike in *Bulox*, UMP and TCC did not waive their argument in this case. The Court also finds the Macks' reliance on the decisions in *Blevins-Ellington v. CooperSurgical, Inc*., No. 1:22-cv-00197-LMM, 2023 WL 2111346 (N.D. Ga. Jan. 17, 2023), and *Bergdoll v. CooperSurgical, Inc*., No. 6:cc-cv-3018-MDH, 2023 WL 2167417 (W.D. Mo. Feb. 22, 2023), to be unpersuasive as well.

UMP and TCC because they are "alter egos" of Femcare and CooperSurgical.

The Eleventh Circuit has recognized that personal jurisdiction may be based on an alter ego theory when a subsidiary's "separate corporate status is formal only" and has no "semblance of individual identity." *Meier*, 288 F.3d at 1272; *Consolidated Dev. Corp. v. Sherritt, Inc*., 216 F.3d 1286, 1293–94 (11th Cir. 2000). But courts do not exercise the power to pierce the corporate veil lightly. *Cont'l Motors, Inc. v. Jewell Aircraft, Inc*., 882 F. Supp. 2d 1296, 1304 (S.D. Ala. 2012) (citing *Gilbert v. James Russell Motors, Inc*., 812 So. 2d 1269, 1273 (Ala. Civ. App. 2001)). And "courts are reluctant to impute the activities of the subsidiary to the parent when some semblance of independence has been maintained." *Kozial v. Bombardier-Rotax GmbH*, 129 F. App'x 543, 547 (11th Cir. 2005) (per curiam). "[M]ere control and dominion does not suffice to trigger alter ego status, . . . [and] Alabama law is clear that the corporate veil cannot be pierced unless the dominant corporation (a) misused that control, and (b) proximately caused harm to the plaintiff through such misuse." *Thornton v. Bayerische Motoren Werke AG*, 439 F. Supp. 3d 1303, 1312–13 (N.D. Ala. 2020) (citations omitted).

The Macks maintain in their brief that UMP and TCC exercise complete control over Femcare and CooperSurgical respectively, citing various public statements connecting the companies with their subsidiaries and attaching several documents showing the interwoven nature of the companies' leadership structures.

But showing the purported requisite level of control is only part of the inquiry. Absent from both the Complaint and the Macks' briefing is any claim that either UMP or TCC *misused* its control of Femcare or CooperSurgical such that piercing the corporate veil is appropriate under Alabama law. And because the Macks "[have] not alleged, much less shown, that [either UMP or TCC] misused its control over [Femcare or CooperSurgical], that such misuse of control harmed [the Macks], or that any injustice or inequitable consequences ensued," their alter ego theory of personal jurisdiction fails. *See Cont'l Motors*, 882 F. Supp. 2d at 1304–05; *Thornton*, 439 F. Supp. 3d at 1312.

2. Femcare

As for Femcare, the Macks argue that because Femcare sold Filshie Clips in 2017 to CooperSurgical and played an active role in the marketing, sale, and distribution of Filshie Clips, and because CooperSurgical in turn sold the clips in Alabama where they were implanted into women including Mrs. Mack, Femcare has sufficient minimum contacts in Alabama for personal jurisdiction. Essentially, the Macks argue that because Femcare entered into a contract with a distributor allowing the sale of Femcare's products in the entire United States, then Femcare is subject to personal jurisdiction in every state in the United States where such clips were sold.

The Eleventh Circuit has considered specific jurisdiction in the product liability context by applying the "stream of commerce" approach. *Vermeulen v.*

Renault, U.S.A., Inc., 985 F.2d 1534, 1546–48 (11th Cir. 1993) ("The forum State does not exceed its powers under the Due Process Clause if it asserts personal jurisdiction over a corporation that delivers its products into the stream of commerce with the expectation that they will be purchased by consumers in the forum State." (quoting *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 297–98 (1980))). In *Ruiz de Molina v. Merritt & Furman Insurance Agency, Inc.*, the Eleventh Circuit articulated the "stream of commerce" test, such that "[t]he stream of commerce test for jurisdiction is met if the nonresident's product is purchased by or delivered to a consumer in the forum state, so long as the nonresident[ ]'s conduct and connection with the forum state are such that he should reasonably anticipate being haled into court there for claims arising out of that conduct." 207 F.3d 1351, 1357 (11th Cir. 2000) (quoting *World-Wide Volkswagen Corp*., 444 U.S. at 298); *see also Simmons v. Big No. 1 Motor Sports, Inc.*, 908 F. Supp. 2d 1224, 1229 (N.D. Ala. 2012) ("By designing the [product] for a manufacturer that distributes nationally in the United States, [the defendant] thereby invoked the benefits and protections of those states, including Alabama. Therefore, 'it is not unreasonable to subject it to suit in one of those States if its allegedly defective merchandise has [] been the source of injury to its owner or to others.'" (quoting *World-Wide Volkswagen Corp*., 444 U.S. at 297)).

The Court finds that Femcare has sufficient minimum contacts in Alabama to be subject to personal jurisdiction in this Court. Femcare is alleged to manufacture and knowingly distribute Filshie Clips to residents of Alabama. Femcare is also alleged to have entered into an exclusive distribution agreement with CooperSurgical who exclusively sold Filshie Clips throughout the United States without limitation, including the state of Alabama, two of which were implanted into Mrs. Mack. As such, Femcare's contacts with Alabama are not random, fortuitous, or the result of a third party's unilateral activity. *Cf. Walden v. Fiore*, 571 U.S. 277, 286 (2014). Instead, "they are the result of [Femcare's] desire to sell its [Filshie Clips] throughout the United States," including Alabama, through its distributor CooperSurgical. *See Collett v. Olympus Med. Sys. Corp.*, 437 F. Supp. 3d 1272, 1281–82 (M.D. Ga. 2020) (concluding that a foreign medical device manufacturer had sufficient minimum contacts with Georgia where manufacturer sold devices throughout the United States, including Georgia, through its affiliated distributors). "A medical device manufacturer like [Femcare] should reasonably expect its [Filshie Clips] to be sold in [Alabama] when it [enters into an exclusive distribution agreement] for the purpose of distributing its [Filshie Clips] throughout the United States and does not exclude [Alabama] from the territories where its [Filshie Clips] may be sold." *See id.* at 1278. Therefore, Femcare should have reasonably anticipated being haled into court in Alabama for claims arising out of its contacts

with Alabama. *See id.* at 1280; *Simmons*, 908 F. Supp. 2d at 1229.

The Macks further allege Femcare provided its own "qualified employee[s]" to CooperSurgical to assist with marketing, training, servicing the products, and for attending conferences with CooperSurgical. Based on the Macks' allegations, Femcare is alleged to have retained control over the sale, distribution, marketing, and safety monitoring of the product. This includes software maintained by Femcare that allows it to track every Filshie Clip that has been sold, including those in Alabama. These allegations further bolster the Court's conclusion that Femcare purposely directed its Filshie Clip-related activities towards Alabama.

Femcare disputes the Macks' allegations and argues the distributors controlled the sales to Alabama. Femcare takes the position that supplying a distributor with its product does not equate to direct contact with Alabama. But as explained above, Femcare contracted with a distributor to sell its Filshie Clips throughout the United States without limitation. Femcare did not restrict the sales of its Filshie Clips to certain states or take steps to prevent their sale in Alabama. Thus Femcare "reasonably expected (or should have reasonably expected) that its [Filshie Clips] . . . would be purchased for use in [Alabama]." *See Collett*, 437 F. Supp. 3d at 1280 (reaching a similar conclusion about device manufacturer's sale of products throughout the United States).

Femcare also argues CooperSurgical has not contested personal jurisdiction,

and as a result, the Macks are not without remedy in Alabama. In light of the above analysis, however, Femcare's arguments fail to persuade the Court that the case should be dismissed against Femcare at this stage.

When a nonresident defendant has sufficient contacts with the forum state, this Court must also consider whether the exercise of specific jurisdiction would "offend 'traditional notions of fair play and substantial justice.'" *Asahi Metal Indus. Co. v. Superior Ct.*, 480 U.S. 102, 113 (1987) (quoting *Int'l Shoe Co*., 326 U.S. at 316). However, Femcare does not argue that subjecting it to jurisdiction in Alabama would "offend 'traditional notions of fair play and substantial justice,'" *see Asahi*, 480 U.S. at 113, and the Court finds no reason to conclude otherwise.

In sum, the Macks have sufficiently established that this Court may exercise personal jurisdiction over Femcare. *See Collett*, 437 F. Supp. 3d at 1282; *Simmons*, 908 F. Supp. 2d at 1231; *see also Wash. Rsch. Found. v. Sanofi*, No. 2:15-cv-1677-BJR, 2016 WL 11261498, *6–7 (W.D. Wash. Aug. 5, 2016) (concluding that a foreign drug manufacturer was subject to personal jurisdiction in the forum state where the manufacturer established a distribution channel to manufacture and ship its product to its subsidiary to sell in the United States, "thereby targeting the forum State").

B. Venue

Aside from contesting personal jurisdiction, Femcare also contests venue.[4]

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 the statute. *See* 28 U.S.C. § 1391(b). A defendant carries 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).

Acknowledging that Femcare is not a resident of Alabama, the Macks contend that a substantial part of the relevant events occurred in the Middle District of Alabama and that Femcare does business in Alabama related to the Macks' claims, thereby making venue proper under § 1391(b)(2). The Court agrees. While Femcare argues that none of its acts or omissions concerning the Macks' claims occurred in this District, the Court has already explained that Femcare's contacts with Alabama are related to the Macks' claims, which the Macks contend arose here. Further, the

[4] CooperSurgical does not make an argument asserting improper venue.

Macks both reside in this District, meaning that at least significant portions of their on-going injuries and treatment have occurred here. Additionally, the Macks assert claims under Alabama state law, and no party has indicated another forum where venue may be more appropriate. Therefore, the Macks have made a sufficient showing that venue is proper in the Middle District of Alabama under § 1391(b)(2), and Femcare has failed to carry its heavy burden of showing that venue is improper, *see Wilson*, 590 F.3d at 1269. Femcare's venue challenge is due to be denied.

C. Preemption and Shotgun Pleading

Next up are Femcare's and CooperSurgical's preemption arguments and CooperSurgical's shotgun pleading argument.

1. Preemption

Under the Medical Device Amendments (MDA), the FDA has regulatory authority over medical devices intended for human use. *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1325 (11th Cir. 2017) (citing 21 U.S.C. § 360c *et seq*.). 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 classified by the FDA as Class III medical devices and accordingly must undergo a rigorous premarket approval process (PMA) before entering the

marketplace in the United States. *Mink*, 860 F.3d at 1325.

PMA requires an applicant to submit detailed reports of studies and investigations regarding their 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; *see also Godelia v. Doe 1*, 881 F.3d 1309, 1317 (11th Cir. 2018). "If the applicant wishes to make such a change, it must submit, and the FDA must approve, an application for supplemental premarket approval, to be evaluated under largely the same criteria as an initial application." *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 obtain and maintain approval.

The MDA preempts state law claims in two ways. *Godelia*, 881 F.3d at 1317. "The express preemption provision bars any claim based on a state law requirement 'which is different from, or in addition to, any requirement' under the MDA that 'relates to the safety or effectiveness of the device' or any other MDA requirement." *Id.* (quoting 21 U.S.C. § 360k(a)). "State requirements are pre-empted under the MDA only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law." *Riegel*, 552 U.S. at 330 (quoting 21 U.S.C. § 360k(a)). The MDA does not expressly preempt state law claims based upon "state duties [that] . . . 'parallel,' rather than add to, federal requirements." *Id.* (citation omitted).

Second, the MDA's implied preemption provision bars claims "that merely

attempt to enforce duties owed to the FDA, so-called 'fraud-on-the-FDA claims.'" *Godelia*, 881 F.3d at 1317 (citing *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001))). The MDA "leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions." *Buckman*, 531 U.S. at 349 n.4; 21 U.S.C. § 337(a). Causes of action not arising from "traditional state tort law which . . . predated the federal enactments in question[]" are preempted. *See Buckman*, 531 U.S. at 353. Specifically, actions arising "solely from the violation of [MDA] requirements," are impliedly preempted because "Congress intended that the MDA be enforced exclusively by the Federal Government." *Id.* at 352.

As the Eleventh Circuit has recognized, "[t]aken together, these two types of preemption leave a 'narrow gap' through which plaintiffs making medical device claims must proceed." *Godelia*, 881 F.3d at 1317 (citation omitted). "To make it through, 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)." *Mink*, 860 F.3d at 1327.

As currently pled, the Macks' state law claims are not impliedly preempted.[5] Although the MDA impliedly preempts "state-law fraud-on-the-FDA claims," *Buckman*, 531 U.S. at 348, it generally does not impliedly preempt "traditional state tort law causes of action that predated the federal enactments[] and did not implicate a duty owed to the FDA," *Mink*, 860 F.3d at 1330 (citing *Buckman*, 531 U.S. at 353). For example, here the Macks' design defect and manufacturing defect claims are based on their contentions that (1) the Filshie Clips used in Mrs. Mack were "defective in design" because their "risk of harm exceed[s] their claimed benefits," specifically as it relates to the device's alleged migration from the implantation site, (Doc. 1 at 14); and (2) the Filshie Clips were "unreasonably dangerous" and "failed to perform as safely as the ordinary consumer would expect, causing injury," (*id.* at 16). Additionally, the Macks' failure to warn claim is based on their contention that the Defendants had a continuing duty to warn the Macks regarding the Filshie Clips' "unreasonable risk of migration" but failed to do so. (*Id.* at 17–18.) The Macks thus rely on "traditional state tort law which had predated the federal enactments," *see Buckman*, 531 U.S. at 353, and their claims do not "implicate a duty owed to the FDA," *see Mink*, 860 F.3d at 1330 (reaching a similar conclusion about Florida state

[5] Only Femcare argued in its initial motion that the Macks' claims were impliedly preempted. CooperSurgical improperly raised its implied preemption arguments for the first time in its reply brief, although the Court notes the Macks were granted leave to file a surreply. *See Hope For Fams. & Cmty. Serv., Inc. v. Warren*, 721 F. Supp. 2d 1079, 1190 n.121 (M.D. Ala. 2010). Assuming without deciding that CooperSurgical's implied preemption arguments were properly before the Court, they fail on the merits for the reasons stated herein.

law claims); *Rice v. Allergan USA, Inc.*, No. 2:16-cv-01374-MHH, 2018 WL 1618036, at *6, *8 (N.D. Ala. Apr. 4, 2018) (concluding that the MDA did not impliedly preempt the plaintiff's negligent design and manufacturing claims or strict liability failure to warn claim, all arising under Alabama law); *Casrell v. Altec Indus., Inc.*, 335 So. 2d 128, 132–33 (Ala. 1976) (expanding the scope of manufacturer liability for design defects in Alabama); *Ex parte Chevron Chem. Co.*, 720 So. 2d 922, 924–25 (Ala. 1998) (citing Restatement (Second) of Torts § 388 (Am. Law. Inst. 1975)) (explaining the "duty to warn end users of the dangers of products" in the negligence context).

Femcare and CooperSurgical insist that because the Macks allege in nearly every count that the Defendants failed to report adverse events about the Filshie Clips to the FDA, the Macks' claims are impermissible "fraud-on-the-FDA" claims and therefore impliedly preempted. The Court is not persuaded. Femcare and CooperSurgical's focus on the allegations regarding the failure to report to the FDA ignores the other allegations that do not implicate a duty owed only to the FDA: that the Defendants owed common law duties *to the Macks* to not negligently design, manufacture, or fail to warn *the Macks* about the alleged dangers of the Filshie Clips. Reading the Complaint as a whole and construing it in the light most favorable to the Macks, the allegations regarding the failure to report to the FDA do not render the Macks' claims impliedly preempted at this stage.

The Macks' state law claims are also not expressly preempted. This Court finds the district court's decision in *Blevins-Ellington v. CooperSurgical, Inc.*, No. 1:22-CV-00197-LMM, 2023 WL 2111346, at *13 (N.D. Ga. Jan. 17, 2023), which reaches a similar conclusion as to Defendants' liability under state law for injuries caused by Filshie Clips, persuasive and instructive on this point. Alabama law permits negligence and strict liability claims against product manufacturers and distributors that rest on common law duties owed to individuals. *See, e.g.*, *Casrell*, 335 So. 2d at 132–33; *Chevron Chem. Co.*, 720 So. 2d at 924–25; *see also Mink*, 860 F.3d at 1331 (making a similar observation about common law duties under Florida law). Like the plaintiffs in *Mink* and *Blevins-Ellington*, the Macks have alleged violations of these state common law duties owed to them. *See Mink*, 860 F.3d at 1333–34; *Blevins-Ellington*, 2023 WL 2111346, at *13. Among others, the Macks assert that the Defendants owed them a duty to prevent manufacturing and design defects, to warn of the risk of harm, and to exercise ordinary care, each of which the Macks connect to parallel federal requirements—for example, the requirement that the Defendants "obtain[] approval for changes in the design, manufacture, and warnings/marketing approved by the FDA." (*E.g.*, Doc. 1 at 16, 18.)

Moreover, as in *Mink* and *Blevins-Ellington*, the Macks "acknowledged the risk of preemption and explicitly limited their pleadings to parallel violations of

federal law." *See Blevins-Ellington*, 2023 WL 2111346, at *13; *Mink*, 860 F.3d at 1329. Thus, based on the Complaint as currently pled, the MDA does not expressly preempt the Macks' state law tort claims for injuries Mrs. Mack allegedly suffered from her Filshie Clips. *See Blevins-Ellington*, 2023 WL 2111346, at *13 (concluding that the MDA does not expressly preempt the plaintiff's Georgia law tort claims for injuries allegedly suffered from Filshie Clips). If the Macks' claims "should later be shown to extend beyond the purview of the applicable federal regulations, [their] claims may be defeated at that point." *See Godelia*, 881 F.3d at 1319. The Court also finds Femcare's and CooperSurgical's remaining arguments regarding express preemption unpersuasive. *See Blevins-Ellington*, 2023 WL 2111346, at *14–15 (rejecting similar express preemption arguments).

2. Shotgun Pleading

CooperSurgical additionally argues that the Macks' Complaint is an impermissible shotgun pleading in that it "assert[s] multiple claims against multiple defendants without specifying which of the defendants are responsible for which acts or omissions." (Doc. 20 at 10 (quoting *Weiland v. Palm Beach Cnty. Sheriff's Office*, 792 F.3d 1313, 1323 (11th Cir. 2015)).) While the Eleventh Circuit has criticized such pleadings, *Weiland*, 792 F.3d at 1321–23, it has also acknowledged that "[t]he fact that defendants are accused collectively does not render [a] complaint deficient," *Kyle K. v. Chapman*, 208 F.3d 940, 944 (11th Cir. 2000). Indeed, a

complaint "can be fairly read to aver that all defendants are responsible for the alleged conduct." *Id.*

Viewing the Complaint and all reasonable inferences in the Macks' favor, the Complaint sufficiently pleads facts establishing a causal connection between the Defendants' actions and the claims against them. According to the Macks, they assert their claims against the Defendants collectively because of the "intertwined business relationship and intertwined facts in the case"—specifically, because the Defendants all allegedly "developed, manufactured, distributed, marketed, and/or sold Filshie Clips during the time they were implanted in Ms. Mack." (Doc. 39 at 12 (quoting *Leo ex rel. Grigsby v. Koch Foods, LLC*, No. 4:20-cv-01997-ACA, 2021 WL 3617699, at *2 (N.D. Ala. Aug. 16, 2021)).) While "discovery may reveal otherwise," a complaint is sufficiently pled so long as "it is plausible that all [defendants] are responsible for the conduct alleged." *Coleman v. Morris-Shea Bridge Co.*, No. 18-cv-00248-LSC, 2019 WL 112213, at *6 (N.D. Ala. Jan. 3, 2019). Although not a model pleading, the Macks' Complaint satisfies this standard, and the "counts are informative enough to permit a court to readily determine if they

state a claim upon which relief can be granted." *See Weiland*, 792 F.3d at 1326.[6]

IV. CONCLUSION

Accordingly, it is hereby ORDERED as follows:

(1) The Motion to Dismiss Plaintiffs' Complaint (Doc. 18) filed by Defendant Utah Medical Products, Inc. is GRANTED for lack of personal jurisdiction. Defendant Utah Medical Products, Inc. is dismissed as a defendant in this matter without prejudice.

(2) The Motion to Dismiss Plaintiffs' Complaint (Doc. 19) filed by Defendant The Cooper Companies, Inc. is GRANTED for lack of personal jurisdiction. Defendant The Cooper Companies, Inc. is dismissed as a defendant in this matter without prejudice.

(3) The Motion to Dismiss Plaintiffs' Complaint (Doc. 20) filed by Defendant CooperSurgical, Inc. is DENIED.

(4) The Motion to Dismiss Plaintiffs' Complaint (Doc. 32) filed by Defendant Femcare, Ltd. is DENIED.

[6] Regarding the statute of limitations, the Defendants have failed to demonstrate at this stage that the Macks' claims are time-barred. *See Blue Cross & Blue Shield of Ala. v. Weitz*, 913 F.2d 1544, 1552 (11th Cir. 1990) (explaining that the defendants bear the burden to establish the applicability of a statute of limitations affirmative defense). A plaintiff is not required to negate a statute of limitations defense in her complaint, and "a Rule 12(b)(6) dismissal on statute of limitations grounds is appropriate only if it is 'apparent from the face of the complaint' that the claim is time-barred." *See La Grasta v. First Union Sec., Inc.*, 358 F.3d 840, 845 (11th Cir. 2004) (citation omitted), *abrogated on other grounds by Twombly*, 550 U.S. at 563. The Defendants have not persuaded the Court that it is so apparent. The Defendants are free to re-raise the statute of limitations issue at summary judgment if appropriate.

DONE, on this the 27th day of March, 2023.

R. AUSTIN HUFFAKER, JR.
UNITED STATES DISTRICT JUDGE