IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA
MINNEAPOLIS DIVISION

MARIA MALO, PLAINTIFF, VS. TORAX MEDICAL, INC., AND ETHICON, INC. DEFENDANTS.	§ § § § § § § § § §	CIVIL ACTION NO. _0:21-cv-2123__ **JURY DEMANDED**

PLAINTIFF'S ORIGINAL COMPLAINT

Plaintiff Maria Malo files this, her Original Complaint, against Defendants Torax Medical, Inc. and Ethicon Inc., and respectfully states follows:

I.

PRELIMINARY STATEMENT

Defendant's Torax Medical, Inc. and Ethicon, Inc. manufactured a defective medical device such that Plaintiff suffered significant injury. Here, a defectively manufactured LINX was surgically implanted in Plaintiff to control her gastroesophageal reflux disease (GERD). After the LINX was implanted in Plaintiff, Defendants became aware of the manufacturing defect in Plaintiff's LINX. Defendants recalled Plaintiff's LINX as well as numerous other LINX devices in the United States and European Union. Moreover, Defendants admit that Plaintiff's LINX was defectively manufactured.

Here, Plaintiff seeks to vindicate her rights at law for having to experience a severe recurrence of her GERD symptoms and undergo another invasive surgery to remove the defective LINX.

II.

PARTIES

1. Plaintiff Maria Malo is a resident of the State of Texas.

2. Defendant Torax Medical, Inc. (Torax) is a Delaware corporation with its headquarters and principal place of business in Shoreview, Minnesota. Torax may be served with process through its registered agent, The Corporation Trust Company at 1209 Orange St., Wilmington, Delaware 19801, or wherever it may be found. While headquartered in Minnesota, Torax's medical devices, including the LINX, are distributed, marketed, sold, and used on medical patients in all fifty United States, including Minnesota, and the European Union. Therefore, Torax is subject to personal jurisdiction in the State of Minnesota.

3. Ethicon, Inc. (Ethicon) is a New Jersey corporation with its headquarters and principal place of business in the State of New Jersey. Ethicon may be served with process through its registered agent Johnson & Johnson, at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933-0000, or its president Nefertiti Green, at Johnson & Johnson, Rt. 22 West, Somerville, New Jersey 08876, or wherever she may be found. While headquartered in New Jersey, Ethicon's medical devices, including the LINX, are distributed, marketed, sold, and used on medical patients in all fifty United States, including Minnesota, and the European Union. Therefore, Ethicon is subject to personal jurisdiction in the State of Minnesota.

III.

JURISDICTION & VENUE

4. This Court has jurisdiction over this proceeding pursuant to 28 U.S.C. § 1332(a)(1). The amount in controversy exceeds $75,000.00.

5. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b)(1) and (2).

IV.

FACTS APPLICABLE TO ALL COUNTS

6. This case arises from the defective manufacturing by Defendants Torax and Ethicon of a medical device known as the "LINX Reflux Management System" ("LINX"). LINX is a titanium bead-and-wire ring surgically implanted around a patient's lower esophageal sphincter (LES) to augment the LES and prevent acid reflux. These devices can only be implanted surgically, and they are used to treat gastroesophageal reflux disease (GERD) which is a disease predominately suffered by the elderly.

 [1]

[1] https://www.jnj.com/innovation/johnson-johnson-medical-innovations-reshaping-future-surgery

7. The LINX required pre-market approval by the Food & Drug Administration prior to it being placed in the stream of commerce and used on patients in the United States and the European Union. Specifically, in December 2010, Defendant Torax applied for this pre-market approval, including its manufacturing process, and this approval was granted on March 22, 2012. The LINX is considered a "restricted" device, meaning it is subject to numerous FDA regulations regarding the manufacture, distribution, and marketing of the device.

8. Defendant Ethicon, Inc. (Ethicon) is the parent-corporation for Defendant Torax and participated in the manufacture, distribution, and post-market surveillance of the LINX.

9. On May 31, 2018, Defendant Torax initiated a recall of numerous LINX due to "an out of specification condition" which would allow "a bead component to separate from an adjacent wire link."[2] This means that the LINX device, normally a continuous loop, would become discontinuous and open due a defect resulting from improper manufacture.

This recall, classified as a Class 2 recall, is considered by the FDA as "a method of removing…products that are in violation of laws" administered by the FDA. FDA records show that there were 9,131 LINX devices in the stream of commerce as of May 2018.

[2] *See* Exhibit "A" – Notice of Recall

10. A 17-bead LINX was surgically implanted in Plaintiff on June 1, 2018. This LINX was subject to the recall described in ¶ 6.

11. Plaintiff the defective LINX was removed on December 2, 2020.

12. Plaintiff alleges that Defendants Torax and Ethicon manufactured the LINX which was implanted in Plaintiff and subsequently failed due to a manufacturing defect. Plaintiff alleges that Defendants Torax and Ethicon placed Plaintiff's LINX device into the stream of commerce. Plaintiff alleges that Defendants Torax and Ethicon are corporations who regularly design, test, assembly, manufacture, sell, and distribute medical devices intended for human use.

V.

CAUSES OF ACTION

A. Manufacturing Defect As to Defendant Torax – Strict Liability

13. Plaintiff incorporates the above paragraphs and would show the Court that she is entitled to recover from, in strict liability for product defect, from Defendant Torax for the defective manufacture of the LINX device surgically-implanted in Plaintiff.

14. Specifically, the LINX implanted in Plaintiff was manufactured in violation of the Federal Food, Drug, and Cosmetic Act, the Medical Device Amendments, and federal regulations promulgated under these laws and administered by the FDA. The device implanted in Plaintiff was manufactured in deviation from the manufacturing specifications approved by the FDA and provided by Defendant Torax for its pre-market approval. Plaintiff's LINX was also manufactured in deviation of Current Good Manufacturing Practice requirements. The LINX was also defectively manufactured in violation of Minnesota law that parallels federal requirements.

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