IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

THREE R LLC, Individually and on Behalf of Itself and all Others Similarly Situated,	:	No. _____
Plaintiff,	:	
-against-	:	**CLASS ACTION COMPLAINT**
CYNOSURE, INC,	:	**JURY TRIAL DEMANDED**
Defendant.	:	

INTRODUCTION

Plaintiff THREE R LLC, ("Plaintiff"), by and through its undersigned attorneys, alleges, upon information and belief, except as to the allegations concerning Plaintiff itself, which Plaintiff alleges upon personal knowledge, as follows:

NATURE OF THE ACTION

1. On July 30, 2018, the United States Food and Drug Administration ("FDA") announced that it had warned several companies to stop marketing laser devices for procedures often and colloquially referred to as "vaginal rejuvenation." As succinctly explained by FDA Commissioner Dr. Scott Gottlieb, the FDA had

> recently become aware of a growing number of manufacturers marketing "vaginal rejuvenation" devices to women and claiming these procedures will treat conditions and symptoms related to menopause, urinary incontinence or sexual function. The procedures use lasers and other energy-based devices to destroy or reshape vaginal tissue. These products have serious risks and don't have adequate

> evidence to support their use for these purposes. We are deeply concerned women are being harmed.

Statement from FDA Commissioner Scott Gottlieb, M.D., on efforts to safeguard women's health from deceptive health claims and significant risks related to devices marketed for use in medical procedures for "vaginal rejuvenation", dated July 30, 2018, available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm615130.htm; *see also* FDA Warns Against Use of Energy-Based Devices to Perform Vaginal 'Rejuvenation' or Vaginal Cosmetic Procedures: FDA Safety Communication, dated July 30, 2018, available at https://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm615013.htm (text of warning) ("July 30, 2018 FDA Warning").

2. As Commissioner Gottlieb further explained, while the FDA had cleared various laser and other energy-based devices to treat such conditions as abnormal or pre-cancerous cervical or vaginal tissue or genital warts, "the safety and effectiveness of these devices hasn't been evaluated or confirmed by the FDA for 'vaginal rejuvenation.'" *Id.* Nonetheless, companies who produce and sell these devices make "deceptive health claims" and engage in "deceptive marketing of a dangerous procedure with no proven benefit," which he stated was, in a word, "egregious." *Id.* As the July 30, 2018 FDA Warning itself stated, using such devices for vaginal rejuvenation "may lead to serious adverse events," including vaginal burns, scarring, pain during sexual intercourse, and recurring/chronic pain. July 30, 2018 FDA Warning.

3. Defendant Cynosure, Inc., ("Defendant" or "Cynosure") is one of the companies that has engaged in this egregious "deceptive marketing of a dangerous product". It has unabashedly marketed and sold its MonaLisa Touch laser system as a vaginal rejuvenation device with promises that it will increase intimacy and improve sexual function – which, as the FDA can hardly have been clearer – are purposes for which it was not approved by the FDA and for which use there is no proven benefit. The MonaLisa Touch is a most expensive device – costing doctors and health practices $150,000 or more.

4. Plaintiff Three R LLC has suffered economic injury directly as a result of Cynosure's false and deceptive marketing scheme. Plaintiff has, for two years, been making payments on a lease to purchase a MonaLisa Touch for purposes of treating vaginal atrophy. The aggregate lease payments exceed $200,000. In light of the July 30, 2018 FDA Warning, Three R LLC can no longer use the MonaLisa Touch unit, although payments on the unit remain due.

5. Accordingly, to address the financial injury caused by Defendant's unlawful deceptive selling of a dangerous medical device for purposes for which the FDA did not approve and for which the device has no proven benefit, Plaintiff brings this action against Cynosure on its own behalf and on behalf of those others similarly situated for breach of the implied warranty of merchantability and fitness for a particular purpose and violation of Massachusetts' Consumer Protection Act, Mass. Gen. Laws ch. 93A and/or other similar laws in effect in other states.

JURISDICTION AND VENUE

6. This Court has Jurisdiction over Plaintiff's claims pursuant to 28 U.S.C. § 1332(d) and the Class Action Fairness Act ("CAFA"). The parties are diverse and the amount in controversy exceeds $5,000,000, exclusive of interest and costs.

7. Plaintiff's claims involve matters of national or interstate interest.

8. Defendant is subject to personal jurisdiction in that Cynosure's principal place of business is in this District.

9. Venue is proper in this district pursuant to 28 U.S.C. § 1391 as Cynosure resides in this District and a substantial part of the events or omissions giving rise to the claims occurred in this District.

THE PARTIES

10. Plaintiff Three R LLC, was, at all relevant times, a limited liability corporation headquartered at 166 Tollgate Road, Suite B, Warwick, Rhode Island 02886. Its owners are all natural persons domiciled the State of Rhode Island.

11. The President of Three R LLC is Robert Salk, DO, a board-certified obstetrician and gynecologist.

12. Cynosure is a corporation incorporated in Delaware, and maintains its principal place of business at 5 Carlisle Road, Westford, MA 01886.

13. Cynosure was and is doing business in the State of Massachusetts, including Middlesex County.

STATEMENT OF FACTS

The MonaLisa Touch

14. The MonaLisa Touch is a laser system manufactured and marketed by Cynosure. The marketing of the device by Cynosure was, upon information and belief, directed from and disseminated by Cynosure from its corporate headquarters in Massachusetts.

15. In its July 24, 2018 letter to Cynosure, Inc. the FDA stated that the MonaLisa Touch had been cleared "for incision, excision, ablation, vaporization and coagulation of body soft tissues in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynaecology, neurosurgery, orthopaedics, general and thorasic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery." July 24, 2018 Letter from Cesar A. Perez, PhD, Chief of the Surveillance and Enforcement Brach, Division of Premarket and Labeling Compliance, Office of Compliance, Center for Devices and Radiological Health to Connie Hoy, Official Correspondent, Cynosure, Inc.

16. On July 30, 2018, the FDA issued a warning in which it stated that it had not "cleared or approved for marketing" the MonaLisa Touch, or any such "energy based devices," for purposes of "vaginal rejuvenation" or "any symptoms related to menopause, urinary incontinence, or sexual function." July 30, 2018 FDA Warning.

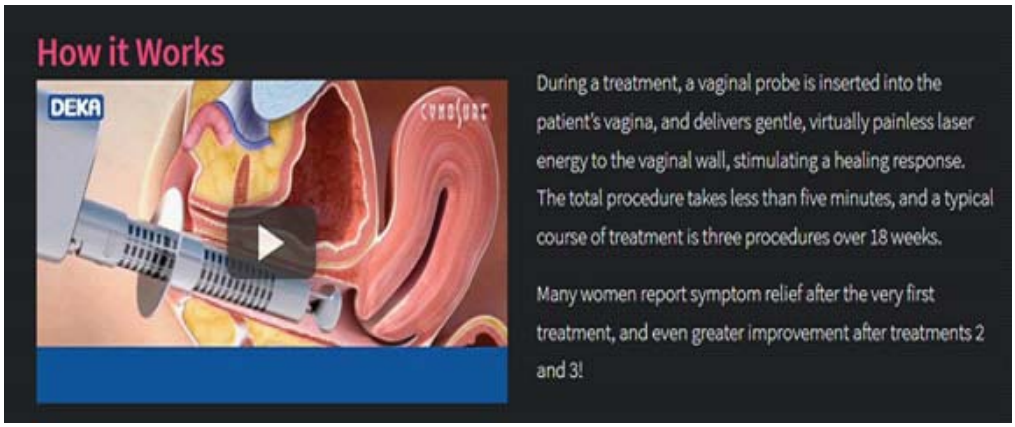
17. The FDA explained that vaginal rejuvenation is "an ill-defined term; however, it is sometimes used to describe non-surgical procedures intended to treat vaginal symptoms and/or conditions including, but not limited to: vaginal laxity; vaginal atrophy, dryness or itching; pain during sexual intercourse; pain during urination; [or]

decreased sexual sensation." *Id.* The term has received substantial popular and colloquial use over the last several years.

Cynosure Markets the MonaLisa Touch As a Vaginal Rejuvenator

18. Cynosure unabashedly markets the MonaLisa Touch as a vaginal rejuvenator.

19. During the relevant period, the MonaLisa Touch's website, www.smilemonalisa.com ("the "Website"), essentially described the MonaLisa Touch as a vaginal rejuvenator and markets it for such uses. It stated that the MonaLisa Touch is "[a] treatment that renews intimacy and changes lives" and "[a] treatment for the painful symptoms of menopause, including intimacy." As depicted on the Website, the MonaLisa Touch contains a probe meant to be inserted into the vagina that shoots a laser onto the vaginal wall:



20. On the Website, Defendant affirmatively represented and stated that "[t]here are virtually no side effects or discomfort with this treatment."

21. The Website featured several testimonials. In "Melinda's Story," a woman on whom the MonaLisa Touch was used stated:

> So, I'm single, & I had gone a little stretch without being in an intimate relationship. And then I was in an intimate relationship and I noticed that I

> kept on pushing away, because it was painful. I thought maybe I wasn't attracted to the person enough, or he wasn't doing his job or something (laugh). You know…seriously. And it really wasn't until later that I started realizing this was my body that was having a reaction, to be honest with you. I actually did notice a difference after my first procedure, and then going back for the second, a huge difference there for me, because I was an unusual case. Then between second and third again just for me you know like a total opening, a softening, receptivity, sensitivity, that I just hadn't had for years and years and years. And so now it's like Yah, bring it on (laugh). Probably what this procedure, the MonaLisa Touch did for me is it gave me back confidence. I'm single, and it made me want to date again. I can feel like I can have a full relationship. So, I feel like I don't have to hold back anymore. I can be spunky, and playful & confident, & alive & vibrant, & just bring everything that I have back to the table, because I think I was holding back. And there's no need to. There's really no need to hold back anymore."

http://www.smilemonalisa.com/melindas-story/. As of this date, the transcript of the Melinda's Story video remains available online, though the Melinda's Story video itself, and other client testimonial videos, was removed from the MonaLisa Touch homepage on or about August 10, 2018.

22. Other marketing materials similarly clarify that the MonaLisa Touch is marketed for, and meant to be used for, vaginal rejuvenation. Accessories for the MonaLisa touch include vaginal probes and vaginal rings. Candidates for the MonaLisa Touch include "[p]atients who present with gynecologic changes due to decrease in estrogen."

23. Nowhere on the Website or other marketing materials does Defendant state that the MonaLisa Touch was not approved for vaginal rejuvenation purposes; to the contrary, Defendant implies that the device has been approved by the FDA for this purpose.

24. Indeed, nowhere on the Website does Defendant materially state or explain or market the MonaLisa Touch for the purposes for which the FDA did, in fact, approve the device for use.

25. Upon information and belief, the MonaLisa Touch is sold or leased by Defendant through related parties throughout the Country. The Website indicates that providers use the MonaList Touch in at least the following states: Alabama, California, Florida, Georgia, Indiana, Illinois, Kentucky, Lousiana, Michigan, New Jersey, New York, North Carolina, Pennsylvania, Rhode Island, Ohio, South Carolina, Tennessee, Texas, and Wisconsin.

Using the MonaLisa Touch for Vaginal Rejuvenation Presents a Significant Risk of Harm

26. On July 30, 2018, the FDA issued a "Safety Communication" entitled, **"**FDA Warns Against Use of Energy-Based Devices to Perform Vaginal 'Rejuvenation' or Vaginal Cosmetic Procedures: FDA Safety Communication." July 30, 2018 FDA Warning."

27. The July 30, 2018 FDA Warning was directed at patients and "health care providers who perform vaginal procedures using energy-based devices." *Id.*

28. It states that treating vaginal rejuvenation "or any symptoms related to menopause, urinary incontinence, or sexual function" through the application of "energy-based therapies to the vagina may lay to serious adverse events, including vaginal burns, scarring, pain during sexual intercourse, and recurring/chronic pain." *Id.*

29. The FDA added that "certain device manufacturers may be inappropriately marketing their energy-based devices for uses," like vaginal rejuvenation, "that are outside of their cleared or approved intended uses." *Id.*

30. The MonaLisa Touch is one such device and Defendant was one of the manufacturers to which the FDA directed its warning. The MonaLisa Touch is a device that can cause serious adverse events, including vaginal burns, scarring, pain during sexual intercourse, and recurring/chronic pain.

31. In marketing and selling the MonaLisa Touch for purposes of vaginal rejuvenation, Cynosure did not disclose that the MonaLisa Touch may be unsafe for vaginal rejuvenation, and, rather, impliedly or expressly represented that it would be safe for vaginal rejuvenation. Cynosure's actions were knowing or willful.

32. Unless enjoined, Cynosure will continue to market and sell the MonaLisa Touch for purposes of vaginal rejuvenation.

Plaintiff Could Not Use the MonaLisa Touch After Its Dangers Were Disclosed

33. Three R LLC's MonaLisa Touch was leased on May 31, 2016 from Heartland Business Credit by Caring for Women, Inc., a related company operating in the same medical office as Three R LLC. The purpose of the lease was to obtain a unit that would treat vaginal atrophy and remedy such atrophy through vaginal rejuvenation. Three R LLC has made all payments on the lease and has received all revenue from operation of the MonaLisa Touch, and is obligated to make all future payments on the lease on behalf of Caring for Women, Inc.

34. The lease was a purchase lease. The total lease payment over a 66 month period is $204,076.00.

35. On August 2, 2018, Caring for Women, Inc. received a letter from Cynosure advising it of the July 30, 2018 FDA Warning.

36. At that point, providers could not use the MonaLisa Touch on patients because if they did so, they would subject patients to potential adverse harms and subject themselves to the possibility of substantial liability. As such, Three R LLC immediately stopped using the MonaLisa Touch.

37. Plaintiff continues to make lease payments for a device that cannot be safely or economically used. The device is unmerchantable and/or unfit for the particular purpose for what it was marketed and sold by Defendant.

CLASS ALLEGATIONS

38. Plaintiff sues on its own behalf and on behalf of on behalf of all purchasers or lessors of the MonaLisa Touch (the DEKA SmartXide Laser System or similar model) nationwide (the "Class"), pursuant to FED. R. CIV. P. 23(a), (b)(2) and (b)(3) seeking to assert the claims set forth below.

39. The Class is so numerous that joinder of all members is impracticable. Although the precise number of MonaLisa Touch owners is unknown, the Website identifies 99 healthcare providers who used the MonaLisa Touch just within 300 miles of Westford, Massachusetts alone. The number sold and identity of all purchasers of the MonaLisa Touch is known to Defendant, is readily identifiable, and can be located through Defendant's records.

40. There are questions of law and fact common to the members of the Class and that predominate over any questions solely affecting the individual members of the Class. Questions of fact and law common to the Class that will materially advance the litigation include, without limitation:

a. Whether Defendant marketed the MonaLisa Touch for vaginal rejuvenation purposes;

b. Whether such purposes were uses unapproved by the FDA for the device;

c. Whether Defendant impliedly or directly represented that the MonaLisa Touch had been approved for such purposes by the FDA or failed to inform those to whom Defendant marketed and sold the MonaLisa Touch that it had not been approved for such purposes by the FDA;

d. Whether the use of the MonaLisa Touch for the unapproved purposes for which Defendant marketed the device presents a threat of possibly causing adverse events, including vaginal burns, scarring, pain during sexual intercourse, and recurring/chronic pain such that the threat of such events renders the device unmerchantable or unfit for its intended purposes;

e. Whether Defendant explicitly or impliedly sold the MonaLisa Touch as a device that did not present a threat of possibly causing adverse events, including vaginal burns, scarring, pain during sexual intercourse, and recurring/chronic pain and/or whether Defendant withheld or omitted such material facts as to the threat of possibly causing such adverse events from those to whom it marketed and sold the device;

f. Whether Cynosure is liable for all damages claimed by Plaintiff and the Class, including, without limitation, compensatory, punitive and/or statutory damages, restitution, interest, costs and disbursements, and attorneys' fees; and

g. Whether Cynosure should be enjoined from continuing to market and sell the MonaLisa Touch in a misleading and deceptive manner, as set forth in this Complaint.

41. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff has the same interests in this matter as all other members of the Class.

42. Plaintiff is an adequate class representative, is committed to pursuing this action and has retained competent counsel experienced in class action litigation.

43. Class certification of Plaintiff's claims is appropriate pursuant to FED. R. CIV. P. 23(b)(2) because Cynosure has acted or refused to act on grounds generally applicable to the Class, making appropriate both declaratory and injunctive relief with respect to the Class. The members of the Class are entitled to injunctive relief to end Cynosure's common and uniform policy under the claims set forth herein.

44. Class certification of Plaintiff's claims is also appropriate pursuant to FED. R. CIV. P. 23(b)(3) because questions of law and fact common to the Class predominate over questions affecting only individual members of the Class, and because a class action is superior to other available methods for the fair and efficient adjudication of this litigation.

45. Plaintiff knows of no difficulty that would be encountered in the management of this litigation that would preclude its maintenance as a class action.

FIRST CLAIM FOR RELIEF:
DECEPTIVE ACTS OR PRACTICES PROHIBITED BY MASSACHUSETTS GEN. LAWS ch.93A AND/OR OTHER SIMILAR LAWS IN EFFECT IN OTHER STATES
(Brought on Behalf of the Class)

46. Plaintiff incorporates by reference paragraphs 1-45 as though fully set forth herein.

47. Cynosure, Plaintiff, and the Class members are "persons" within the meaning of Mass. Gen. Laws ch. 93A, § 1(a).

48. Cynosure is engaged in "trade" or "commerce" within the meaning of Mass. Gen. Laws ch. 93A, § 1(b).

49. The Massachusetts unfair trade practices protection law ("Massachusetts Act") prohibits "unfair or deceptive acts or practices in the conduct of any trade or commerce." Mass. Gen. Laws ch. 93A, § 2.

50. In the course of its business, Cynosure, through its agents, employees, and/or subsidiaries, violated the Massachusetts Act as detailed in this Complaint. Specifically, in marketing, offering for sale, and selling the MonaLisa Touch for vaginal rejuvenation purposes notwithstanding that it was not approved by the FDA for those purposes and notwithstanding that such use presented a risk of harm to those patients upon whom the device would be used, Cynosure engaged in one or more of the following unfair or deceptive acts or practices as prohibited by Mass. Gen. Laws ch. 93A, § 2:

a. Causing likelihood of misunderstanding as to the fitness and safety of the MonaLisa Touch for purposes of vaginal rejuvenation;

b. Representing that the MonaLisa Touch has approval, characteristics, uses, or benefits that it does not have;

c. Representing that the MonaLisa Touch is of a particular standard, quality and grade when it is not; and/or

d. Using or employing deception, fraud, false pretense, false promise or misrepresentation, or the concealment, suppression or omission of a material fact with intent that others rely upon such concealment, suppression or omission, in connection with the advertisement and sale of the Mona Lisa Touch, whether or not any person has in fact been misled, deceived or damaged thereby.

51. Defendant's scheme and concealment of the true characteristics of the MonaList Touch were material to Plaintiff and the Class, as Defendant intended. Had they known the truth, Plaintiff and the Class would not have purchased or leased the MonaLisa Touch, or—if the MonaLisa Touch's true nature had been disclosed—would have paid significantly less for the MonaLisa Touch or leased it for significantly less.

52. Plaintiff and the Class members had no way of discerning that Cynosure's representations were false and misleading, or otherwise learning the facts that Cynosure had concealed or failed to disclose, because Plaintiff and the Class did not have access to Cynosure's knowledge about the nature and fitness of the MonaLisa Touch when used for vaginal rejuvenation. Plaintiff and the Class members did not, and could not, unravel Cynosure's deception on their own and, to the contrary, could and did rely on Cynosure's expertise as a maker and seller of medical devices.

53. Cynosure had an ongoing duty to Plaintiff and the Class to refrain from unfair and deceptive practices under the Massachusetts Act in the course of its business. Specifically, Cynosure owed Plaintiff and Class members a duty to disclose all the

material facts concerning the MonaLisa Touch because it possessed exclusive knowledge that it intentionally concealed it from Plaintiff and the Class, and/or it made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

54. Plaintiff and the Class members suffered ascertainable loss and actual damages as a direct and proximate result of Cynosure's concealment, misrepresentations, and/or failure to disclose material information.

55. Cynosure's violations present a continuing risk to Plaintiff and the Class, as well as to the general public. Cynosure's unlawful acts and practices complained of herein affect the public interest.

56. Plaintiff and the Class seek an order pursuant to Mass. Gen. Laws ch. 93A § 9 enjoining Cynosure's unfair and/or deceptive acts or practices, and awarding damages, punitive damages, and any other just and proper relief available under the Massachusetts Act.

SECOND CLAIM FOR RELIEF:
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE
(Mass. Gen. Laws Ch. 106 §§ 2-314 and 2A-212 AND/OR OTHER SIMILAR LAWS IN EFFECT IN OTHER STATES)
(Brought on Behalf of the Class)

57. Plaintiffs incorporate by reference paragraphs 1-45 as though fully set forth herein.

58. Cynosure was at all relevant times a "merchant" with respect to the MonaLisa Touch under Mass Gen. Laws ch. 106 § 2-104(1) and is a "seller" under § 2-103(1) (d) and/or other similar laws in effect in other states.

59. The MonaLisa Touch is and was at all relevant times "goods" within the meaning of Mass. Gen. Laws ch. 106 §§ 2-105(1) and 2A-103(1)(h) and/or other similar laws in effect in other states.

60. A warranty that the MonaLisa Touch was in merchantable condition and fit for its ordinary purpose for which it was used and/or for which it was intended to be used by Defendant in selling it is implied by law pursuant to Mass. Gen. Laws ch. 106 §§ 2-314 and 2A-212 and/or other similar laws in effect in other states.

61. Cynosure sold the MonaLisa Touch though the MonaLisa Touch was not merchantable and/or fit for the purpose for which it was intended to be used by Defendant in violation of these implied warranties.

62. Cynosure's breaches of the implied warranty of merchantability and/or fitness for a particular purposes caused damage to the Plaintiff and the Class. The amount of damages due will be proven at trial.

PRAYER FOR RELIEF

Wherefore, Plaintiff, on behalf of itself and all others similarly situated, pray for judgment against Defendant as follows:

A. For an Order certifying the Class and any other appropriate subclasses thereof under the appropriate provisions of Federal Rule of Civil Procedure 23, and appointing Plaintiff and its counsel to represent such Classes and subclasses as appropriate under Rule 23(g);

B. For injunctive relief;

C. For compensatory, equitable, and/or restitutionary damages according to proof and for all applicable statutory damages under the causes of action set forth herein;

D. For an award of attorneys' fees and costs;

E. For prejudgment interest and the costs of suit; and

F. For such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiff demands a trial by jury on all questions of fact raised by the Complaint.

Dated: August 13, 2018
Rye Brook, NY

By:_____

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