

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

<b>LAURA NUDEL,</b>  <i>Plaintiff,</i>	<b>Case No. 1:24-cv-12495</b>
<b>V.</b>  <b>HOLOGIC, INC.,</b>  <i>Defendant.</i>	<b>JURY TRIAL DEMANDED</b>

**COMPLAINT**

Plaintiff, Laura Nudel (“Plaintiff”), brings this action against Defendant Hologic, Inc. (“Defendant” or “Hologic”), a Massachusetts corporation.

**VENUE AND JURISDICTION**

Venue is proper in this Court pursuant to 28 U.S.C. §§ 101, 1391, 1441(a), because (1) Defendant resides in this judicial district; and (2) a substantial part of the events or omissions giving rise to the claim occurred in this district. This Court has subject matter jurisdiction under 28 U.S.C. § 1332(a) because (1) there is complete diversity of citizenship between Plaintiff and Defendant; and (2) the amount in controversy exceeds \$75,000, exclusive of interests and costs.

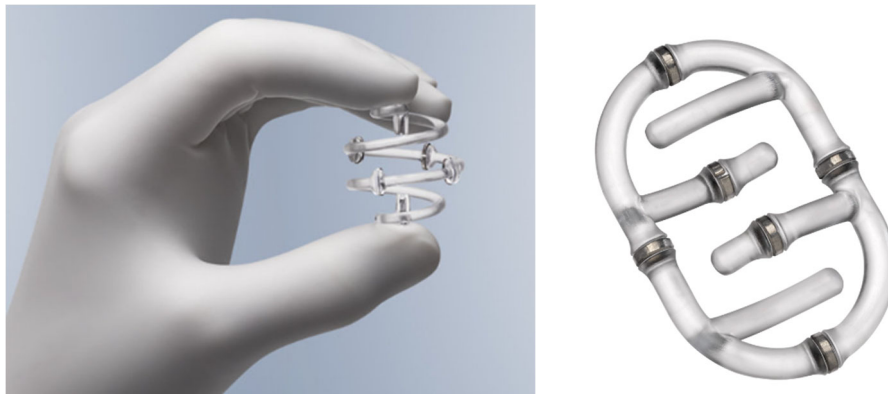
**INTRODUCTION**

1. Plaintiff, a breast cancer survivor, was implanted with a device called BioZorb (“BioZorb” or “BioZorb Marker”) that was manufactured by Hologic.

2. BioZorb is an implantable medical device. It is a unique three-dimensional radiographic bioabsorbable marker used to mark soft tissue sites. The most common use of the

BioZorb is to mark radiation therapy site(s) in a patient's breast following breast cancer lumpectomy, which is how the device was used in Plaintiff's case.

3. The bulk of BioZorb device, which is the circular or spiral component (pictured below) is bioabsorbable compound made primarily of polylactic acid. The device is embedded with six (6) titanium radiopaque marker clips that serve as "targets" for radiation therapy. The bioabsorbable spacer material is supposed to be resorbed by the body leaving the radiopaque clips as a permanent indicator of the soft tissue site.



4. This lawsuit is a personal injury action against Defendant Hologic who is responsible for designing, researching, developing, testing, manufacturing, packaging, labeling, marketing, promoting, distributing, and/or selling of the BioZorb.

### **PARTIES**

#### **Plaintiff**

5. Plaintiff is, and at all relevant times was, a citizen and resident of the State of Pennsylvania and the United States and over the age of eighteen (18) years.

6. Plaintiff was diagnosed with breast cancer in or around August, 2021. She underwent a lumpectomy in her left breast on or around September 30, 2021, at UPMC Harrisburg in Harrisburg, Pennsylvania, during which a BioZorb LP (F0221) was properly implanted by Dr. Lisa K. Torp, MD.

7. Plaintiff suffered from injuries at and around the site of the BioZorb device. Plaintiff suffers from a hardened mass and scar tissue near the site of the implantation of the BioZorb and can “feel” what she believes is likely the non-absorbed device in her left breast. She has also recently been diagnosed with scar tissue and fat necrosis at the site of the implant. She has had severe pain, reddening, and a hot/burning sensation in her breast tissue over the past year-and-a-half and she cannot push, pull, pick up objects, or even move without pain, which radiates throughout her left breast. Plaintiff is actively seeking further treatment and anticipates the need for future surgery to remove the BioZorb and possibly her entire left breast due to the pain and scarring.

8. Additionally, as a result of the pain, complications, and hardened mass from the BioZorb device, Plaintiff fears the possibility of another tumor, causing her significant emotional distress.

9. As a result of the BioZorb, Plaintiff has been caused to have significant pain, disfigurement, and worry, leaving her permanently and physically scarred. Plaintiff’s complications, adverse local tissue reaction, disfigurement, non-absorption, and palpable mass are not warned of on the Instructions for Use but were risks Defendant knew, or should have known, and failed to disclose to physicians and patients.

### **Defendant**

10. Defendant Hologic is headquartered in Marlborough, Massachusetts which was, and is, engaged in the business of designing, manufacturing, developing, preparing, processing, inspecting, testing, packaging, promoting, marketing, distributing, labeling, or selling for profit, either directly or indirectly, through an agent, affiliate, predecessor, or subsidiary, the BioZorb device. Hologic is registered to do business in, and routinely does business through employees, contractors, and agents, and enjoys protection of the laws of both Massachusetts and Pennsylvania.

11. The BioZorb device is a class II medical device first cleared by the FDA in 2012. BioZorb is a tissue marker and is an implantable device developed to mark the surgical site of tissue removal in three dimensions. It has six (6) titanium marker clips distributed in a three-dimension (3D) pattern inside a bioabsorbable polylactic acid (PLA) coil, in either a helical or low profile (LP) flat, oval option, that is intended to facilitate the identification and delivery of more focused radiation therapy.

### **BACKGROUND AND FACTS**

#### **A. Background on BioZorb**

12. The BioZorb is a Class II medical device cleared by the United States Food and Drug Administration (“FDA”) in February 2012 pursuant to Section 510(k) of the Food and Drug, and Cosmetic Act (“510(k)).

13. BiZorb is a three-dimensional implantable radiographic marker. It is comprised of a bioabsorbable spacer that holds six radiopaque titanium clips. The bioabsorbable spacer material (polylactic acid) is intended to be resorbed in the body by hydrolysis, leaving the radiopaque clips as permanent indicators of the soft tissue site.

14. The BioZorb’s Instructions for Use (“IFU”) (including all accompanying warnings), of which the same or substantially same applied to Plaintiff at the time of her implant, are illustrated below:

## BioZorb® Marker, BioZorb® LP Marker

### Instructions for Use

#### DESCRIPTION

The Marker is a radiographic implantable marker used to mark soft tissue.

It is comprised of a bioabsorbable spacer that holds Titanium radiopaque marker clips. The bioabsorbable spacer material (poly lactic acid) is resorbed by the body leaving the radiopaque clips as a permanent indicator of the soft tissue site.

The Marker may be used with the following imaging modalities: X-Ray (CT, mammography), MR and ultrasound.

The bioabsorbable spacer is resorbed by a process of hydrolysis whereby the degradation products of the spacer material are metabolized by the body. The spacer material retains its functional integrity for approximately 2 months, while complete resorption may require up to one or more years.

#### INDICATIONS

The Marker is indicated for radiographic marking of sites in soft tissue. In addition, the Marker is indicated in situations where the soft tissue site needs to be marked for future medical procedures.

#### CONTRAINDICATIONS

The Marker should not be placed in a tissue site with clinical evidence of infection.

#### WARNINGS

- The Marker should only be used by physicians trained in surgical techniques. The physician is responsible for its proper clinical use.
- The Marker is shipped sterile; do **NOT** re-sterilize any portion of the Marker.
- The Marker is for **SINGLE USE** only.
- Do **NOT** use if the package is open or damaged, or if the temperature indicator has a black center.
- Use the Marker prior to the expiry date shown on the product label.

#### PLACEMENT OF MARKER

##### PREPARATION

- 1) Remove the Marker from the sterile packaging
- 2) Visually inspect the product for any damage.

##### INSERTION

- 1) Using sterile technique, place the Marker in the desired tissue site.
- 2) Suture the marker to adjacent tissue at multiple locations as desired for secure positioning
- 3) Where required, close the surgical cavity using standard surgical technique.

#### DISPOSAL PROCEDURES

When necessary, dispose of any product in accordance with local regulations.

#### STORAGE

Store at room temperature. Avoid storing the Marker at conditions of excessive heat or humidity. If the temperature indicator has a black center, do not use product. Handle with care. Packages should be stored in a manner that protects the integrity of the package and the sterile barrier.

#### MRI SAFETY INFORMATION

Non-clinical testing has demonstrated the BioZorb® Marker / BioZorb® LP Marker is MR Conditional. A patient with this device can be safely scanned in an MR system under the following conditions:

- Static magnetic field of 1.5 T; Maximum spatial field gradient of 1,900 gauss/cm (19 T/m); Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode); 15 minutes of continuous scanning

Under the scan conditions defined above in non-clinical testing, the Marker was shown to produce a maximum temperature rise of less than 1.6°C. In addition, the image artifact caused by the marker clip of the device extended an average of 3.8mm from the Marker when imaged with a gradient echo and spin echo pulse sequence and a 1.5T MRI system. MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the implant. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

#### HOLOGIC®



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MAN-07631 Rev. 001

15. The FDA rejected clearing BioZorb for the indication that it provides a reference from which treatment (e.g. radiotherapy) can be guided.

16. Defendant marketed BioZorb as a device that can fill space in breast tissue, improve cosmetic outcomes after procedures, and guide radiotherapy. The FDA did not clear any of these indications for use.

**B. The Problems with BioZorb and the Inadequacy of the Instructions for Use**

17. The IFU for BioZorb contains no warnings or contraindications of any substance to effectively warn patients, physicians, or hospitals of the relevant risks associated with the use of the device.

18. The BioZorb IFU and Defendant's marketing of the BioZorb indicate the device is intended to completely resorb in up to one or more years. However, there is evidence that the device can take significantly longer than one year to absorb, or it may fail to absorb at all. These risks are not mentioned in the IFU.

19. Hologic was aware of Medical Device Reports ("MDRs") that reported patient complications including, but not limited to, infection, fluid buildup, device migration, device erosion, pain, discomfort, rash, extended resorption time of the device, and additional surgeries. These risks are not mentioned in BioZorb's IFU.

20. Hologic also knew, or should have known, of clinical evidence that BioZorb can cause a hard, palpable lump causing patient pain and discomfort. These risks are not mentioned in BioZorb's IFU.

21. Hologic also knew, or should have known, of clinical evidence that shows that BioZorb may increase a patient's radiation dose, contributing to further complications. As one breast surgery noted, "[n]ormally, a lumpectomy cavity is treated for 5 fractions with low energy

electrons such as 6 MeV or 9MeV. Such energies give modest doses to the skin and leave no permanent scarring. As you increase in energy electrons, it increases the skin dose and you run the risk of seeing more early and late skin reactions. The most disfiguring side effect [of using the BioZorb device] is the appearance of telangiectasias, which look like red spider veins. These risks are not mentioned in BioZorb's IFU.

22. Hologic also knew, or should have known, of clinical evidence that the device was causing infection, migration, necrosis, additional radiation, and additional surgery. These risks are not mentioned in BioZorb's IFU.

**C. FDA Issues a Safety Communication Regarding Potential Risks of Using BioZorb Markers in Breast Tissue.**

23. On February 2, 2024, the U.S. Food and Drug Administration issued a Safety Communication ("February 27 Notice") regarding BioZorb Markers.

24. The February 27 Notice informed patients, healthcare providers, and hospitals about the potential risk of serious complications when using BioZorb Markers manufactured by Hologic.

25. The FDA issued the February 27 Notice after receiving reports describing complications (adverse events) with the use of BioZorb Markers in breast tissue including infection, fluid buildup (seroma), device moving out of position (migration), device breaking through the skin (erosion), pain, discomfort from feeling the device in the breast, rash, other complications "possibly associated with" extended resorption time (resorbable component of the device not resorbing in the patient's body for several years), and the need for additional medical treatment to remove the device.

26. The FDA noted in the February 27 Notice that it had cleared BioZorb Markers for radiographic marking of sites in soft tissue (including breast) or for marking the soft tissue site for future medical procedures.

27. In the February 27 Notice, the FDA stated that it had not cleared or approved the BioZorb Markers to fill space in the tissue or to improve cosmetic outcomes after procedures.

28. From its entry into the market, Defendant marketed and promoted the BioZorb Markers to hospitals and surgeons as a device that fills space in breast tissue and improves cosmetic outcomes following surgery.

29. Surgeons relied on the Defendant's representations and implanted BioZorb Markers in patient, including Plaintiff.

30. Hospitals relied on Defendant's representations and allowed use of BioZorb Markers in patients, including Plaintiff.

31. The FDA noted that Defendant had not provided any data to support its claim that the device improved cosmetic outcomes.

**D. FDA Class I Recall of BioZorb Marker.**

32. On March 13, 2024, pursuant to FDA direction, Hologic sent an Important Medical Device Safety Notification ("Safety Notification") to affected customers.

33. The Safety Notification was to request that patients contact their healthcare provider if they experience any adverse events following the placement of a BioZorb Marker; report any problems or complications experienced following the placement of the BioZorb Marker devices to Hologic and to the FDA's MedWatch Adverse Event Reporting program; and discuss the benefits and possible risks of implantable breast tissue markers for breast cancer procedures with their health care provider.



34. The Important Medical Device Safety Notification was also required to be sent to healthcare providers, and Hologic requested that the healthcare providers be aware of serious adverse events following possible risks of BioZorb Marker devices with each patient; inform all patients on which device will be used if a marking device will be used during breast conservation surgery; continue to monitor patients who have an implanted BioZorb Marker for signs of any adverse events; and report any problems or complications experienced by patients following placement of the BioZorb Marker devices to Hologic and the FDA's MedWatch Adverse Event Reporting program.

35. On May 22, 2024, the FDA classified Hologic's communications to its customers as a Class I recall.

36. Class I recalls are the most serious type of recall.

37. The FDA further noted that the use of BioZorb Markers may cause serious injuries or death.

38. The FDA indicated that this recall was a correction, not a product removal.

39. Complaints that led to the recall included reports of pain, infection, rash, device migration, device erosion, seroma, discomfort, or other complications from feeling the device in the breast, and the need for additional medical treatment to remove the device.

### **CAUSES OF ACTION**

#### **COUNT I – STRICT LIABILITY AND/OR NEGLIGENT FAILURE TO WARN**

40. Plaintiff incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein.

41. At all relevant times, Defendant designed, tested, manufactured, marketed, labeled, distributed, and sold the BioZorb device.

42. Defendant expected that, and the BioZorb was indeed, sold and implanted in Plaintiff without a substantial change in condition.

43. Defendant sold the BioZorb in a defective condition in that it contained inadequate warnings regarding the unreasonably dangerous condition of the BioZorb.

44. Defendant knew and intended for the BioZorb device to be implanted into individuals for whom the device is indicated, including Plaintiff.

45. Defendant had a duty to produce a product that contained adequate warnings and had a duty to disclose the dangers and risks of the BioZorb device, which Defendant knew, or in the exercise of ordinary care, should have known, at the time the BioZorb device left their control.

46. Defendant knew, or in the exercise of ordinary care, should have known that the BioZorb device could cause the injuries suffered by Plaintiff because Defendant was aware of post-marketing adverse event reports, otherwise known as Medical Device Reports (“MDRs”), that alleged the same or substantially similar injuries that were suffered by the Plaintiff in this lawsuit.

47. Moreover, Defendant was aware that BioZorb was designed in such a way that, following implant, it would perform in the recipient’s body in a way that was not consistent with what Defendant stated in the product’s instructions for use, and in a way that posed an unreasonably dangerous risk profile for patients.

48. The BioZorb device was not accompanied by proper warnings and instructions to physicians and the public regarding potential adverse side effects associated with the implantation of the device and the comparative severity and duration of such adverse side effects.

49. Specifically, the BioZorb’s IFU (Instructions for Use) failed to include warnings that the BioZorb device may take several years to (and in some cases, may never) dissolve in the breast and need to be surgically removed. The warnings also failed to include information that a

radiologist might need to use a higher energy electron therapy which can cause scarring on the breast.

50. The IFU also failed to adequately warn that the BioZorb is associated with chronic and/or serious adverse effects, including chronic and/or severe pain, infection, rash, device migration, device erosion, seromas, chronic discomfort, feeling of a lump in the breast (lack of resorbed device), and other complications related to lack of absorption of the device in the breast.

51. The IFU also failed to warn that the aforementioned adverse effects pose a significant risk of subsequent surgical treatment to remove the device and/or otherwise pose a risk of clinically significant sequelae including mass formation, infectious buildup, scarring, fat necrosis, adverse tissue reaction, and extrusion of the device from breast skin and tissue.

52. The above clinically significant issues and their association with the BioZorb device were known or knowable by the Defendant at the time the device was implanted into Plaintiff, which necessitated warnings, but Defendant failed to place such warnings in the IFU.

53. Had Plaintiff been warned of the aforementioned serious adverse effects, she would not have chosen to receive the BioZorb device and would have worked in conjunction with her implanting physician to receive an alternative treatment and/or device.

54. Defendant also marketed BioZorb in a manner beyond its indications for use, for example, to fill space in breast tissue and/or improve cosmetic outcomes after procedures, and participated in other “off label” promotional activities.

55. Defendant’s sales representatives used “off label” promotional activities while also with failing to disclose to physicians the risks of BioZorb, which caused physicians, including Plaintiff’s physician, to recommend to Plaintiff the BioZorb device while also holding an incomplete or otherwise inaccurate perception of its risk/benefit analysis.

56. Had Defendant disclosed the true risks of the BioZorb device to Plaintiff's physician, then this would have altered Plaintiff's implanting physician's risk/benefit analysis and would have caused Plaintiff's implanting physician to recommend an alternative treatment and/or device and/or would have caused Plaintiff to elect an alternative device.

57. As a direct and proximate result of Defendant's conduct, Plaintiff has suffered serious physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

58. WHEREFORE, the Plaintiff demands judgment against Defendant and seeks compensatory damages where applicable, together with costs and interest, and any further relief as the Court deems proper, as well as a trial by jury of all issues to be tried.

## **COUNT II – STRICT LIABILITY AND/OR NEGLIGENT DESIGN DEFECT**

59. Plaintiff incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein.

60. At all relevant times, Defendant designed, researched, developed, inspected, tested, packaged, labeled, distributed, supplied, and/or sold BioZorb.

61. Defendant expected that, and the BioZorb was indeed, sold and implanted in Plaintiff without a substantial change in condition.

62. The design of the BioZorb is defective and unreasonably dangerous because of its design aspects, including, but not limited to, its shape, surface, texture, material, and integration of parts. The design aspects of the BioZorb could have been feasibly changed to make the device less harmful and not unreasonably dangerous.

63. There are technologically feasible and practical alternative designs that would have reduced or prevented Plaintiff's harm.

64. In the oncological surgical market, alternative designs exist that are mechanically feasible, safer, and cost significantly less than BioZorb.

65. For example, titanium clips that have been on the market for years carry less clinical risk to the patient. In fact, at least one clinical study has found that the use of clips to mark a cancer patient's tumor bed is more cost effective and advantageous than the use of BioZorb.

66. The BioZorb's design poses a high gravity of danger, beyond that of the reasonable consumer's contemplation. The risks of the design of BioZorb device outweigh the benefits of its design aspects. For example, if the BioZorb does not fully absorb in the body after 1 year or more, which is a common adverse occurrence which is not warned about in the IFU, it poses an unreasonable risk of migration, infection, chronic seroma and/or fluid buildup, chronic pain, and/or the device becomes a chronic "mass" that must be surgically removed.

67. The design of the BioZorb device was a substantial factor in causing harm to Plaintiff.

68. WHEREFORE, Plaintiff demands judgement against Defendant and seeks compensatory damages where applicable, together with costs and interest, and any further relief as the Court deems proper, as well as a trial by jury of all issues to be tried.

### **COUNT III – BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY**

69. Plaintiff incorporates by reference all preceding paragraphs of this Complaint as is fully set forth herein.

70. Defendant designed, researched, developed, inspected, tested, packaged, labeled, distributed, supplied, and/or sold BioZorb with an implicit warranty that the BioZorb was fit for the ordinary purpose for which it was used, and, in Plaintiff's case, the use in which the BioZorb was warranted was to be used as a radiation marker following breast cancer lumpectomy.

71. Defendant impliedly warranted to prospective purchasers and users, including Plaintiff, that the BioZorb device was safe, merchantable, and fit for the ordinary purposes for which said product was to be used.

72. Plaintiff reasonably relied upon the skill and judgement of Defendant as to whether the BioZorb device was of merchantable quality and safe and fit for its intended use.

73. Upon information and belief, and contrary to such implied warrants, the BioZorb device was not of merchantable quality or safe and fit for its intended use, because the product was and is unreasonably dangerous and unfit for the ordinary purposes for which it was used, as described above.

74. Further, Restatement (Second) of Torts Section 402A, comment “k”, does not bar the Plaintiff’s breach of implied warranty claim based on the Defendant’s presumed position that the medical device at issue was unavoidably unsafe.

75. Defendant marketed BioZorb to fill space in breast tissue, to improve cosmetic outcomes after procedures, and to provide radiotherapy guidance, all in direct contravention of the Indications for Use cleared by the FDA.

76. Defendant marketed BioZorb to fill space in the breast tissue, improve cosmetic outcomes after procedures, or to provide radiotherapy guidance, all in contravention of the Indications for Use cleared by the FDA, of which Defendant knew or should have known.

77. As a direct and proximate result of Defendant’s conduct, Plaintiff has suffered serious physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

78. WHEREFORE, Plaintiff demands judgment against Defendant and seeks compensatory damages where applicable, together with costs and interest, and any further relief as the Court deems proper, as well as a trial by jury of all issues to be tried.

#### **COUNT IV – NEGLIGENCE**

79. Plaintiff incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

80. At all times material hereto, Defendant, directly or indirectly, created, manufactured, assembled, designed, sterilized, tested, packaged, labeled, marketed, promoted advertised, sold and/or distributed into the stream of commerce the BioZorb device including the one implanted in Plaintiff.

81. Under federal and state law and regulation, Defendant was under a continuing duty to test and monitor the BioZorb device as well as their component parts, design, and manufacturing processes after premarket approval. The duties included establishing and validating its quality control systems and product suppliers, testing the device design, and investigating and reporting to the FDA any complaints about the device's performance and any malfunctions of which Defendant became aware and that are or may be attributable to the BioZorb device. See 21 C.F.R. Part 803; 21 C.F.R. Part 814; 21 C.F.R. Part 820; 21 U.S.C. §§ 351(h), 360i.

82. Defendant was negligent in designing, manufacturing, researching, developing, preparing, processing, packaging, promoting, marketing, labeling, supplying, inspecting, testing, distributing, and selling the BioZorb by failing to use reasonable care in fulfilling their duty to avoid foreseeable dangers.

83. Defendant was negligent in failing to comply with federal and state law, and failing to use reasonable care in fulfilling their duty to inform users of dangerous risks, including risks posed by the device's negligent design. As a result of the foregoing conduct, Plaintiff's physicians, and hospitals were sold defective medical devices without knowing the true risk-benefit ration of the BioZorb.

84. Defendant knew or should have known that the risk of the BioZorb was different than what was in the IFU and communicated to patients, physicians, and hospitals.

85. Defendant knew or should have known that the BioZorb's benefits differed from what was marketed, promoted, advertised, and communicated to patients, physicians, hospitals, and the general public.

86. Defendant knew or should have known that the FDA did not clear the BioZorb marker to fill space in the breast tissue, improve cosmetic outcomes after procedures, or provide radiotherapy guidance.

87. Despite this knowledge, Defendant marketed the BioZorb to fill space in breast tissue, to improve cosmetic outcomes after procedures, and to provide radiotherapy guidance, all in direct contravention of the Indications for Use cleared by the FDA.

88. It was readily foreseeable to Defendant that Plaintiff and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and failure to report material information regarding the device's risks and claimed benefits. Defendant knew that Plaintiff and her physician and hospitals would use the medical device for its intended purpose, that their intended use would pose a substantial health risk to Plaintiff, and that Plaintiff, and the medical community would rely on Defendant's representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant the BioZorb.

89. Under the same or similar circumstances, a reasonable manufacturer would have warned through an appropriate channel and medium of communication of the danger and reported the risks of BioZorb to patients, physicians, and hospitals.

90. Had Defendant adequately tested BioZorb, evidence regarding the device's risks, the rate of occurrence, and the extent of harm regarding each risk would have been found and could have been communicated to patients, physicians, and hospitals.



91. Had Defendant employed safety monitoring and pharmacovigilance measures for BioZorb, it could have mitigated or eliminated the risks posed by the BioZorb.

92. Had Defendant timely reported the known risks associated with the BioZorb to patients, physicians, and hospitals and allowed them to make informed decisions about using an alternative product that did not present the same risks, or foregoing the use of any marker, Plaintiff would not have been implanted with BioZorb.

93. Defendant knew that BioZorb's design was defective yet failed to take reasonable measures to mitigate or eliminate the risks posed by the defective design.

94. As a direct and proximate result of Defendant's actions and omissions, Plaintiff suffered injuries, including but not limited to physical pain, infection, subsequent surgeries, and emotional injuries.

95. As a result of the above negligence, Plaintiff suffered pain, medical expenses, emotional distress, and other economic and non-economic damages.

96. WHEREFORE, Plaintiff demands judgment against Defendant and seeks compensatory damages where applicable, together with costs and interest, and any further relief as the Court deems proper, as well as a trial by jury of all issues to be tried.

**PRAYER FOR RELIEF AS TO ALL COUNTS**

WHEREFORE, Plaintiff respectfully prays for judgment against the Defendant as follows:

- a. Judgment in favor of Plaintiff and against Defendant, for damages in such amounts as may be proven at trial;
- b. Compensation for both economic and non-economic losses, including, but not limited to, medical expenses, loss of earnings, pain and suffering, mental anguish, and emotional distress, in amounts as may be proven at trial;
- c. Punitive and/or exemplary damages in such amounts as may be proven at trial;
- d. Attorneys' fees, expenses, and costs of this action;

- e. Pre- and Post-judgment interest as provided by law; and
- f. Any and all further relief, both legal and equitable, that the Court may deem just and proper.

**JURY DEMAND**

Plaintiff demands a trial by jury as to all issues herein.

Dated: September 30, 2024

Respectfully submitted,

/s/ Michael Appel

Michael Appel, Esq.

Massachusetts Bar ID No. 543898

Robert Price, Esq. (*pro hac vice to be filed*)

Florida Bar No. 0085284

Keith E. Smith, Esq. (*pro hac vice to be filed*)

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## CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

## I. (a) PLAINTIFFS

Laura Nudel

(b) County of Residence of First Listed Plaintiff Dauphin County, PA  
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number)

Michael Appel, Ketterer, Browne & Associates, LLC, 336  
S. Main Street, Bel Air, MD 21014, (410) 885-6267

## DEFENDANTS

Hologic, Inc.

County of Residence of First Listed Defendant \_\_\_\_\_  
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF  
THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

## II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant ☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

## III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- |   | PTF                                   | DEF                        |   | PTF                        | DEF                                   |
|---|---------------------------------------|----------------------------|---|----------------------------|---------------------------------------|
| Citizen of This State                   | <input type="checkbox"/> 1            | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State     | <input type="checkbox"/> 4 | <input checked="" type="checkbox"/> 4 |
| Citizen of Another State                | <input checked="" type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input type="checkbox"/> 5            |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3            | <input type="checkbox"/> 3 | Foreign Nation  | <input type="checkbox"/> 6 | <input type="checkbox"/> 6            |

## IV. NATURE OF SUIT (Place an "X" in One Box Only)

Click here for: [Nature of Suit Code Descriptions.](#)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	<b>PERSONAL INJURY</b> <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice <b>PERSONAL INJURY</b> <input type="checkbox"/> 365 Personal Injury - Product Liability <input checked="" type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability <b>PERSONAL PROPERTY</b> <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other <b>LABOR</b> <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act <b>IMMIGRATION</b> <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 <b>PROPERTY RIGHTS</b> <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 835 Patent - Abbreviated New Drug Application <input type="checkbox"/> 840 Trademark <input type="checkbox"/> 880 Defend Trade Secrets Act of 2016 <b>SOCIAL SECURITY</b> <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) <b>FEDERAL TAX SUITS</b> <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 376 Qui Tam (31 USC 3729(a)) <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit (15 USC 1681 or 1692) <input type="checkbox"/> 485 Telephone Consumer Protection Act <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
<b>REAL PROPERTY</b> <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	<b>CIVIL RIGHTS</b> <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education <b>PRISONER PETITIONS</b> <b>Habeas Corpus:</b> <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <b>Other:</b> <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement			

## V. ORIGIN (Place an "X" in One Box Only)

- ☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District (specify) ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

## VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):  
28 U.S.C. Section 1332(a)  
Brief description of cause:  
Product liability

## VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND \$

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No

## VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE Allison D. Burroughs

DOCKET NUMBER 1:23-cv-13215

DATE

9/30/2024

SIGNATURE OF ATTORNEY OF RECORD

/s/ Michael Appel

## FOR OFFICE USE ONLY

RECEIPT # \_\_\_\_\_ AMOUNT \_\_\_\_\_ APPLYING IFP \_\_\_\_\_ JUDGE \_\_\_\_\_ MAG. JUDGE \_\_\_\_\_

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

1. Title of case (name of first party on each side only) Laura Nudel v. Hologic, Inc.
2. Category in which the case belongs based upon the numbered nature of suit code listed on the civil cover sheet. (See local rule 40.1(a)(1)).
- ☐ I. 160, 400, 410, 441, 535, 830\*, 835\*, 850, 880, 891, 893, R.23, REGARDLESS OF NATURE OF SUIT.
- ☐ II. 110, 130, 190, 196, 370, 375, 376, 440, 442, 443, 445, 446, 448, 470, 751, 820\*, 840\*, 895, 896, 899.
- ☒ III. 120, 140, 150, 151, 152, 153, 195, 210, 220, 230, 240, 245, 290, 310, 315, 320, 330, 340, 345, 350, 355, 360, 362, 365, 367, 368, 371, 380, 385, 422, 423, 430, 450, 460, 462, 463, 465, 480, 485, 490, 510, 530, 540, 550, 555, 560, 625, 690, 710, 720, 740, 790, 791, 861-865, 870, 871, 890, 950.
- \*Also complete AO 120 or AO 121. for patent, trademark or copyright cases.
3. Title and number, if any, of related cases. (See local rule 40.1(g)). If more than one prior related case has been filed in this district please indicate the title and number of the first filed case in this court.
- Evers v. Hologic, Inc., 22-11895
4. Has a prior action between the same parties and based on the same claim ever been filed in this court?
- YES ☐ NO ☒
5. Does the complaint in this case question the constitutionality of an act of congress affecting the public interest? (See 28 USC §2403)
- YES ☐ NO ☒
- If so, is the U.S.A. or an officer, agent or employee of the U.S. a party?
- YES ☐ NO ☒
6. Is this case required to be heard and determined by a district court of three judges pursuant to title 28 USC §2284?
- YES ☐ NO ☒
7. Do all of the parties in this action, excluding governmental agencies of the United States and the Commonwealth of Massachusetts ("governmental agencies"), residing in Massachusetts reside in the same division? - (See Local Rule 40.1(d)).
- YES ☒ NO ☐
- A. If yes, in which division do all of the non-governmental parties reside?
- Eastern Division ☒ Central Division ☐ Western Division ☐
- B. If no, in which division do the majority of the plaintiffs or the only parties, excluding governmental agencies, residing in Massachusetts reside?
- Eastern Division ☐ Central Division ☐ Western Division ☐
8. If filing a Notice of Removal - are there any motions pending in the state court requiring the attention of this Court? (If yes, submit a separate sheet identifying the motions)
- YES ☐ NO ☐

(PLEASE TYPE OR PRINT)

ATTORNEY'S NAME Michael Appel, KBA AttorneysADDRESS 336 S. Main Street, Bel Air, MD 21014TELEPHONE NO. 855-522-5297