April 24, 2025

Mentor Worldwide LLC
Alicia Botham
Senior Program Lead
31 Technology Drive
Irvine, California 92614

Re: K242963
Trade/Device Name: MENTOR™ PliaForm™ Breast Tissue Expander w/ Suture Tabs
Regulatory Class: Unclassified
Product Code: LCJ
Dated: March 14, 2025
Received: March 19, 2025

Dear Alicia Botham:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Alicia Hemphill -S

Digitally signed by Alicia Hemphill -S
Date: 2025.04.24 15:43:44 -05'00'

Alicia Hemphill (Johnson), M.S.
Assistant Director
DHT4B: Division of Plastic and Reconstructive Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K242963

Device Name
MENTOR™ PliaForm™ Breast Tissue Expander w/ Suture Tabs

Indications for Use *(Describe)*
The MENTOR™ PliaForm™ Breast Tissue Expander w/ Suture Tabs can be utilized for breast reconstruction after mastectomy, correction of an underdeveloped breast, scar revision and tissue defect procedures. The expander is intended for temporary subcutaneous or submuscular implantation and is not intended for use beyond six months.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY
(K242963)

I. SUBMITTER

Mentor Worldwide LLC
31 Technology Drive
Irvine, CA 92614

Contact Person:
Alicia Botham
Regulatory Sr. Program Lead
Phone: 828-775-0302
ABotham1@its.jnj.com

Date Prepared: April 24, 2025

II. DEVICE

Name of Device	MENTOR™ PliaForm™ Breast Tissue Expander w/ Suture Tabs
Common Device Name	Expander, Skin, Inflatable
Classification	Unclassified, Pre-Amendment
Regulation	Unclassified, Pre-Amendment
Panel	General & Plastic Surgery
Product Code	LCJ

III. PREDICATE DEVICE

K161176, Mentor Artoura™ Smooth Breast Tissue Expanders

This predicate has not been subjected to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The PliaForm™ Breast Tissue Expander w/ Suture Tabs is designed for breast reconstruction, designed for thinner components and a reduction of reinforcement features and minimized insertion profile. The integrated port design consists of a plastic needle guard and a smaller magnetic element to improve MR compatibility (MR Conditional). The next generation design control technology (DCT) facilitates predictable expansion and is shape-optimized to better match the entire implant portfolio. An improved Bufferzone features a new sheeting-based self-sealing technology that offers protection from inadvertent needle punctures across the entire coverage area, and a more flexible design, which improves the overall device flexibility. An internally fixated injection port reduces device bulkiness. The injection port will incorporate a new plastic needle guard with a silicone backing and smaller magnet with reduced magnetic field strength compared to the Artoura™ breast tissue expander devices. This feature reduction improves device compatibility with MR-CT imaging, and external beam radiation (such as photon beam).

Identification of the injection port site is accomplished by use of the CENTERSCOPE™ 2.0 Magnetic Injection Port Locator, which is provided with the Tissue Expander. When the Centerscope™ 2.0 device is placed on top of the skin, the magnetic arm points to the center of the tissue expander's injection port. Injections into the injection port area are made using the provided infusion needle set to inject sterile, pyrogen-free Sodium Chloride U.S.P. Solution.

The MENTOR™ PliaForm™ Breast Tissue Expander w/ Suture Tabs incorporates suture tabs to provide surgeons with the option to attach the device to surrounding tissue for enhanced device stability.

The MENTOR™ PliaForm™ Breast Tissue Expander w/ Suture Tabs are provided sterile in three styles (Low Height, Medium Height, and Tall Height) and various sizes.

The following accessories are packaged with the MENTOR ™ PliaForm™ Breast Tissue Expander w/ Suture Tabs:

- Centerscope™ 2.0 Magnetic Injection Port Finder
- Winged Infusion Set (21G)

V. INDICATIONS FOR USE

The MENTOR™ PliaForm™ Breast Tissue Expander w/ Suture Tabs can be utilized for breast reconstruction after mastectomy, correction of an underdeveloped breast, scar revision and tissue

defect procedures. The expander is intended for temporary subcutaneous or submuscular implantation and is not intended for use beyond six months.

VI. COMPARISON OF TECHOLOGICAL CHARACTERISTICS WITH PREDICATE

The technological principle for both the proposed and predicate devices is the same. The expansion in both devices is based on incremental filling of a silicone shell with saline fluid to stretch the surrounding tissue. Filling is achieved via an integral injection site (port) with needle guard, and a magnetic injection port finder to locate the port.

The following table summarizes the technological and design features in the predicate and the proposed devices:

FEATURE	PROPOSED DEVICE (PliaForm™)	PREDICATE DEVICE (Artoura™, K161176)
Injection Port	With following updates: • Redesigned for internal attachment • Needle guard material change to plastic with silicone backing • Smaller magnet for expander to be MR Conditional	Injection port with magnet and needle guard, surrounded by silicone bufferzone, compatible with 21G needle
Self-Sealing Buffer Zone	With following updates: • use of new sheeting-based self-sealing technology • Updated geometry	Silicone elastomer/Dacron mesh subassembly filled with silicone gel
Design Control Technology (DCT) Components	With following update(s): • Updated geometry to accommodate shell shape and updated materials	Internal Legs and Insert to provide structural support
Shell	With following update(s): • Thinner three-layer smooth silicone elastomer sheeting with identical patient-contacting surface	Smooth Silicone Elastomer Sheeting
Orientation Mark	With following update(s): • Blue silicone ink pad printed on 6 o'clock tab (covered by layer of patient-contacting silicone elastomer	Palpable mark (indent) on 6 o'clock suture tab

Suturing Tabs	With the following update(s):	Tabs at 3, 6, 9, o'clock with suturing holes
	• Additional tabs with suturing holes at 1:30, 4:30, 7:30, and 10:30.	

VII. PERFORMANCE DATA

Biocompatibility Testing:

The MENTOR™ PliaForm™ Breast Tissue Expander is an implantable device, the contact category according to ISO 10993-1 is: Implant, tissue contacting, permanent (> 30 days). All patient-contacting materials used in the MENTOR™ PliaForm™ Breast Tissue Expander are identical to the materials used in the predicate device. Mentor qualified the introduction of new materials with biocompatibility testing, including full analytical characterization. Results from testing and biocompatibility risk analysis concluded no change in the biocompatibility safety profile, compared to the predicate device.

Mechanical Testing:

Mechanical testing was conducted in accordance with ASTM F1441-03, Standard Specification for Soft-Tissue Expanders. The following mechanical testing were performed:

ASTM Reference (if applicable)	Document	Description
ASTM F1441-03 -Section 9.2.5	TM000388	Valve Functionality and Device Leakage
ASTM F1441-03 -Section 9.2.8.2	TM000401	Determination of Joint Bond Strength (Shell/Bufferzone)
ASTM F1441-03 -Section 9.2.8.1	TM000401	Determination of Joint Bond Strength (Shell/Patch)
ASTM F1441-03 -Section 9.2.8.2	TM000401	Determination of Joint Bond Strength (Shell/Insert)
ASTM F1441-03 -Section 9.2.8.2 / Section 9.2.2.2	TM000019	Determination of Tensile/Elongation Properties of Elastic Materials (Legs/Bufferzone Joint)
ASTM F1441-03 -Section 9.2.8.2 / Section 9.2.2.2	TM000019	Determination of Tensile/Elongation Properties of Elastic Materials (Legs/Base Joint)
ASTM F1441-03 -Section 9.2.2.1	TM000406	Shell Tension Set
ASTM F1441-03 -Section 9.2.2.2	TM000019	Determination of Tensile/Elongation Properties of Elastic Materials (Shell)
ASTM F1441-03 -Section 9.2.7	101031807	Needle Stop Penetration
ASTM F1441-03 -Section 9.2.4	TM000386	Injection Site (Dome) Leakage
N/A	TM000412	Bufferzone Self-Sealing
N/A	101040589	Needle Guard Detachment Force
N/A	100899657	Suture Tab Tear

All mechanical performance testing results met their pre-determined acceptance criteria, thus demonstrating that the proposed device is substantially equivalent to the predicate device.

Non-Clinical Testing - MR/CT/RT Qualification:
Mentor reduced specific features in the predicate design (Artoura™) to improve device compatibility with MR-CT imaging, and external beam radiation (e.g., photon beam) for radiation therapy. Mentor qualified this capability by performing MR safety related tests including induced force, induced torque and induced heating. Furthermore, Mentor conducted device integrity testing post MR, CT and RT exposures.

Mentor performed physical device integrity testing on PliaForm™ expanders after expanders were exposed to photon beam radiation therapy dosage of 80 Gy. Radiation treatments post mastectomy typically are 1.8 – 2Gy per fraction, with a total radiation treatment dose of approximately 66.6 Gy assuming 33 treatments. Accounting for 120% hot spot, 80 Gy was taken as worst-case representation of clinical radiation therapy exposure. Post radiation exposure, PliaForm™ expanders were shown to meet physical property testing per ASTM F1441-03 "*Standard Specification for Soft-Tissue Expander Devices*", including tests related to overexpansion, injection port competence, shell break force, shell tensile set and joint testing. Additional testing included self-sealing of the BUFFERZONE™ patch and the ability to sufficiently locate the injection port using the CENTERSCOPE™ 2.0 port locator.

Mentor performed an assessment of radiation dose distribution in a preclinical phantom model using Volumetric Modulated Arc Therapy (VMAT) using commercial radiation planning software. Three metrics were evaluated in one experiment using two different size expanders, including homogeneity index (HI), conformity index (CI) and quality of coverage (QOC) to quantify dosimetry distribution. Results for PliaForm™ were compared to results of the sham control (phantom without any expander) and were found to be within 5% of dosimetry values. .

VIII. CONCLUSION

The MENTOR™ PliaForm™ Breast Tissue Expander is substantially equivalent to the legally marketed predicate device, MENTOR™ Artoura™ Breast Tissue Expander with Smooth surface (K161176). The MENTOR™ PliaForm™ Breast Tissue Expander has the same intended use, indications for use, operating principle and technological characteristics as the predicate device. Like the predicate, the MENTOR™ PliaForm™ Breast Tissue Expander meets all performance testing specifications. The successful performance evaluations demonstrate the subject device is substantially equivalent to the predicate device