January 12, 2025

Mentor Worldwide LLC
Catherine Carvalho
Associate Director Regulatory Affairs
31 Technology Drive
Irvine, California 92618

Re: K243836
Trade/Device Name: Mentor™ CPX ™ 4 PLUS Enhance Breast Tissue Expander
Regulatory Class: Unclassified
Product Code: LCJ
Dated: December 12, 2024
Received: December 13, 2024

Dear Catherine Carvalho:

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: 2025.01.12 18:06:37 -06'00'

Alicia L. Hemphill, M.S.
Assistant Director
DHT4B1: 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)*
K243836

Device Name
Mentor™ CPX ™ 4 PLUS Enhance Breast Tissue Expander

Indications for Use *(Describe)*
The MENTOR™ CPX™4 PLUS Enhance Smooth Breast Tissue Expander with fill volume to 1445cc can be used for breast reconstruction after mastectomy, correction of an underdeveloped breast, scar revision and tissue defect procedures. The devices are intended for temporary subcutaneous or submuscular implantation and are 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

MENTOR WORLDWIDE LLC

SPECIAL 510(k) Breast Tissue Expander: **510(k) Summary**

510(k) SUMMARY

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the Mentor CPX™4 Large Smooth Breast Tissue Expanders, with fill volumes up to 1445 cc is provided below.

I. SUBMITTER

Mentor Worldwide LLC
31 Technology Drive
Irvine, CA 92618

Contact Person:
Catherine Carvalho
Associate Director, Regulatory Affairs
Phone: 508-880-8412
ckilshaw@its.jnj.com

Date Prepared: December 3, 2024

II. DEVICE

Name of Device: Mentor ™ CPX™4 PLUS Enhance Breast Tissue Expanders (with fill volumes up to 1445 cc)

Common Device Name: Expander, Skin, Inflatable

Classification Regulation: Unclassified, Pre-Amendment

Panel: General & Plastic Surgery

Product Code: LCJ

III. PREDICATE DEVICE

K241918, Mentor™ CPX™4 PLUS Enhance Breast Tissue Expander with fill volumes up to 1445cc
This predicate has not been subjected to a design-related recall.

K152496, Mentor™ CPX™4 Breast Tissue Expander with fill volumes up to 1445cc
This predicate has not been subjected to a design-related recall.

IV. DEVICE DESCRIPTION

The MENTOR™ CPX™4 PLUS Enhance Breast Tissue Expander is used for breast reconstruction following mastectomy and is intended for temporary subcutaneous or submuscular implantation and is not intended for use beyond six months. The proposed device consists of a smooth surface shell made with successive cross-linked layers of silicone elastomer identical to the predicate device (K241918). Again, identical to the predicate device, the subject device contains superior and anterior reinforcement which allows for directional expansion in the lower pole of the device. The device has an integral, silicone elastomer, magnetically detected, injection dome and incorporates a BUFFERZONE™ area with self-sealing technology (containing silicone gel) to the front patch of the device to minimize and/or prevent leakage in the event of an accidental needle puncture. The CPX™4 PLUS Enhance Breast Tissue Expander Injection Dome houses a rare-earth, permanent magnet. This internal magnet, when in conjunction with the CENTERSCOPE™ Magnetic Injection Port Locator accessory, helps the injector accurately identify the injection dome during patient tissue expander fill procedures.

Identification of the injection dome site can be accomplished by use of the CENTERSCOPE™ Magnetic Injection Port Locator provided with the Tissue Expander. Instructions for use of the CENTERSCOPE™ Magnetic Injection Port Locator are provided within this document. Injections must be made using sterile, pyrogen-free Sodium Chloride U.S.P. Solution and into the injection dome area. If injections are made on or outside the injection dome, leakage can occur.

The MENTOR™ CPX™4 PLUS Enhance Smooth Breast Tissue Expander will continue to give surgeons the option to attach the device to surrounding tissue to enhance device stability. Surgeons can suture on any part of the tab surface or the suturing hole can be used for added convenience.

The MENTOR™ CPX™4 PLUS Enhance Smooth Breast Tissue Expander, Catalogue Number SCPX-15TH-E, is proposed to provide fill volume options from 850 cc to 1445 cc.

The following accessories are packaged with the CPX™4 PLUS Enhance Breast Tissue Expander:

- Centerscope Magnetic Injection Port Finder
- Winged Infusion Set

V. INDICATIONS FOR USE

The MENTOR™ CPX™4 PLUS Enhance Smooth Breast Tissue Expander with fill volume to 1445cc can be used for breast reconstruction after mastectomy, correction of an underdeveloped breast, scar revision and tissue defect procedures. The devices are

intended for temporary subcutaneous or submuscular implantation and are not intended for use beyond six months.

VI. COMPARISON OF TECHOLOGICAL CHARACTERISTICS WITH PREDICATE

The proposed device has the same scientific technology, principles of operation, Intended Use, and Indications for Use as the cleared predicate device, MENTOR™ CPX™4 PLUS Enhance Breast Tissue Expanders with fill volumes up to 1445cc (K241918). The subject of this special 510(k) is to expand the lower limit fill volume of the subject device to match the predicate device (K152496) to 850cc.

The technological principle for both the proposed and predicate devices is the same. All devices' expansion are based on incremental filling of a silicone shell with saline fluid to stretch the surrounding tissue. Filling is achieved via an integral injection dome with needle guard, and a magnetic injection finder to locate the dome. The proposed device has the same scientific technology, principles of operation, Intended Use, and Indications for Use as the cleared predicate device, CPX™4 PLUS Enhance Breast Tissue Expander with fill volumes to 1445cc (K241918).

This special 510(k) pre-market notification is expanding the lower limit fill volume of the existing tissue expander (K241918) from 930cc to 850cc to match the range cleared for the predicate device, CPX™4 Breast Tissue Expander with fill volumes to 1445cc (K152496). The MENTOR™ CPX™4 PLUS Enhance Breast Tissue Expander will continue to be provided sterile and deflated. All components, device features and specifications remain unchanged.

VII. PERFORMANCE DATA

Biocompatibility Testing:

The MENTOR™ CPX™4 PLUS Enhance Breast Tissue Expander with fill volume to 1445cc is an implantable device; the contact category according to ISO 10993-1:2018 is: Implant, tissue contacting, permanent (> 30 days). All materials used in the proposed CPX™ 4 PLUS Enhance Breast Tissue Expander will fill volumes 850cc to 1445cc are identical to the materials used in the predicate device (fill volumes 930cc-1445cc). All patient contact materials are identical to the predicate device. No changes associated with the proposed device warrant new biocompatibility testing.

Mechanical Testing:

No new mechanical testing was conducted on the proposed CPX™4 PLUS Enhance expander with fill volumes 850cc to 1445cc. Mechanical testing was previously conducted on the predicate CPX™4 PLUS Enhance expander with fill volumes 930cc to 1445cc (K241918). The previous testing performed evaluated parameters related to overexpansion and bladder leak testing in accordance with ASTM F1441-03, *Standard Specification for Soft-Tissue Expanders*, at a label fill volume of 1445cc. All mechanical performance testing

that was previously conducted met their pre-determined acceptance criteria. A label fill volume of 1445cc represents a worst case volume for conducting overexpansion and bladder leak testing for CPX™4 PLUS Enhance, as a higher fill volume results in more internal pressure within the device. Thus, reducing the lower limit fill volume for CPX™4 PLUS Enhance from 930cc to 850cc does not require any additional mechanical testing given that it was previously demonstrated that CPX™4 PLUS Enhance has the ability to meet pre-determined mechanical performance testing requirements at a volume up to and including 1445cc.

VIII. CONCLUSION

The proposed CPX™4 PLUS Enhance Breast Tissue Expander with fill volumes from 850 cc to 1445 cc has the same intended use, operating principle and technological characteristics as the predicate devices. This change is simply to align with the predicate device K152496. Performance evaluations demonstrate that the subject device is substantially equivalent to the predicate device, CPX™4 PLUS Enhance Breast Tissue Expander with fill volume 930cc to 1445cc, (K241918) and CPX™4 Breast Tissue Expander with fill volumes to 1445cc (K152496).