



August 2, 2024

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

Re: K241918

Trade/Device Name: MENTOR™ CPX™4 PLUS Enhance Breast Tissue Expander

Regulation Number: 21 CFR 878.5030

Regulation Name: Natural Nonabsorbable Silk Surgical Suture

Regulatory Class: Class II

Product Code: GAP

Dated: June 28, 2024

Received: July 1, 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.

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

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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

Indications for Use

510(k) Number (if known)

K241918

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.

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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 gives 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, provides fill volume options from 930 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 TECHNOLOGICAL 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 Breast Tissue Expanders with fill volumes up to 1445cc (K152496) and MENTOR™ CPX™4 Tissue Expander with Smooth Surface (K182335).

The technological principle for both the proposed and predicate devices is the same. Both 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 Breast Tissue Expander with fill volumes to 1445cc (K152496).

This special 510(k) pre-market notification describe a change to the surface of the tissue expander (from textured to smooth) and the addition of three suture tabs for a total of six suture tabs like the CPX™4 Smooth Tissue Expander cleared via K182335. The MENTOR™ CPX™ 4 PLUS Enhance Breast Tissue Expander is provided sterile and deflated. The predicate MENTOR™ CPX™4 Textured Surface device (K152496) is provided in Tall Height Style with fill volume up to 1445cc like the proposed device. All other 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 are identical to the materials used in the predicate device. All patient contact materials are identical to the predicate device. No changes associated with the proposed device warrant new biocompatibility testing.

Mechanical Testing:

Mechanical testing was conducted on the modified device in order to demonstrate substantial equivalence with the predicate device. This testing was performed as required by the risk analysis and in accordance with design control procedures. The testing performed evaluated parameters related to overexpansion and bladder leak testing in accordance ASTM F1441-03, *Standard Specification for Soft-Tissue Expanders*. Since the proposed CPX™4 PLUS Enhance Breast Tissue Expanders with Smooth Surface will have a smooth outer surface, the connection of the external components relative to the shell surface will change. Specifically, the Base and Injection Dome components will be attached to the smooth surface (not the textured surface) of the shell.

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

VIII. CONCLUSION

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