September 25, 2018

Mentor Worldwide LLC
c/o Mr. Martin Sprunck
Associate Director, Regulatory Affairs
33 Technology Drive
Irvine, California 92618

Re: K182335
Trade/Device Name: CPX 4 Breast Tissue Expander with Smooth Surface
Regulatory Class: Unclassified
Product Code: LCJ
Dated: August 27, 2018
Received: August 28, 2018

Dear Mr. Sprunck:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 5: Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K182335

Device Name

Mentor® CPX™4 Breast Tissue Expanders with Smooth Surface

Indications for Use *(Describe)*

The CPX™4 Breast Tissue Expanders with Smooth Surface 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.

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FORM FDA 3881 (7/17) Page 1 of 1

Section 6: 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 Breast Tissue Expanders with Smooth Surface device is provided below.

I. SUBMITTER

Mentor Worldwide LLC
33 Technology Drive
Irvine, CA 92618

Contact Person:

Martin Sprunck
Associate Director, Regulatory Affairs
Phone: 949-789-8589
Fax: 949-450-6886
msprunc9@its.jnj.com

Date Prepared: August 27, 2018

II. DEVICE

Name of Device:	MENTOR® CPX™4 Breast Tissue Expander with Smooth Surface
Common Device Name:	Expander, Skin, Inflatable
Classification	Unclassified, Pre-Amendment
Review Panel:	General & Plastic Surgery
Product Code:	LCJ

III. PREDICATE DEVICE

K130813, Mentor® CPX™4 Breast Tissue Expanders and Mentor® CPX™4 with Suture Tabs Breast Tissue Expanders

IV. DEVICE DESCRIPTION:

The CPX™4 Tissue Expanders with Smooth Surface consist of a silicone elastomer shell, with superior and anterior reinforcement that allows for directional expansion in the lower pole of the device. The device has an integral, silicone elastomer, magnetically detectable injection port. The injection port also incorporates a BUFFERZONE® area with self-sealing technology which is attached to the inside of the anterior surface of the device. The BUFFERZONE® is intended to minimize and/or prevent leakage in the event of an accidental needle puncture.

Identification of the injection port site is accomplished by use of the CENTERSCOPE® Magnetic Injection Port Locator, which is provided with the Tissue Expander. When the Centerscope device is placed on top of the skin, the magnetic arm points to the center of the tissue expander's injection dome. Injections into the injection dome area

are made using the provided infusion needle set to inject sterile, pyrogen-free Sodium Chloride U.S.P. Solution.

The CPX™4 Tissue Expanders with Smooth Surface incorporate suture tabs to provide surgeons with the option to attach the device to surrounding tissue for enhanced device stability.

The CPX™4 Tissue Expanders with Smooth Surface are provided sterile. The devices are provided in three styles (Low, Medium and Tall) and in various sizes.

The following accessories are packaged with the CPX™4 Tissue Expanders with Smooth Surface:

- Centerscope Magnetic Injection Port Finder
- Winged Infusion Set

V. INDICATIONS FOR USE:

The CPX™4 Tissue Expanders with Smooth Surface 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 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 and Mentor® CPX™4 with Suture Tabs Breast Tissue Expanders (K130813).

The technological principle for both the proposed and predicate devices is the same. Expansion of both the proposed and predicate 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 dome with needle guard, and a magnetic injection finder to locate the dome.

This 510(k) pre-market notification describes changes to the predicate's device shell surface. The predicate and proposed devices will be manufactured with identical components, however the CPX™4 Tissue Expanders with Smooth Surface will have a smooth exterior surface while the predicate device has a textured exterior surface. In addition, the proposed CPX™4 Tissue Expanders with Smooth Surface will incorporate a total of six suture tabs while the predicate device configuration with suture tabs includes a total of three suture tabs. All other device features and specifications remain unchanged. The brand name of the proposed device is CPX™4 Tissue Expanders with Smooth Surface.

PERFORMANCE DATA:

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. Since the proposed CPX™4 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.

Testing evaluated parameters related to joint strength and overexpansion in accordance with ASTM F1441-03, *Standard Specification for Soft-Tissue Expanders.*

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

Biocompatibility Assessment:
The Mentor® CPX™4 Tissue Expanders with Smooth Surface are implantable devices. The contact category according to ISO 10993-1 is: Implant, tissue contacting, permanent (> 30 days). All materials used in the Mentor® CPX™4 Tissue Expanders with Smooth Surface 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.

VII. CONCLUSION:

Mentor® CPX™4 Tissue Expanders with Smooth Surface are substantially equivalent to the predicate device, Mentor® CPX™4 Breast Tissue Expander (K130813). Mentor® CPX™4 Breast Tissue Expanders with Smooth Surface have the same indications for use, same intended use, same fundamental technology, operating principle and technological characteristics as the Mentor® CPX™4 Expanders (predicate device). Performance evaluations demonstrate that the subject device is as safe and effective as the predicate device. Mentor® CPX™4 Breast Tissue Expanders with Smooth Surface are therefore substantially equivalent to the predicate Mentor® CPX™4 Breast Tissue Expanders (K130813).