



Food and Drug Administration
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May 23, 2016

Mentor Worldwide LLC
Ms. Laura Vellucci
Regulatory Affairs Fellow
33 Technology Drive
Irvine, California 92618

Re: K161176

Trade/Device Name: ARTOURA™ Breast Tissue Expanders With Smooth Surface
Regulatory Class: Unclassified
Product Code: LCJ
Dated: April 25, 2016
Received: April 26, 2016

Dear Ms. Vellucci:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Jennifer R. Stevenson -A

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K161176

Device Name

MENTOR Artoura Breast Tissue Expander with Smooth Surface

Indications for Use (Describe)

The Mentor® Artoura™ 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.

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

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510(k) SUMMARY

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the MENTOR® ARTOURA™ Breast Tissue Expanders with Smooth Surface is provided below.

I. SUBMITTER

Mentor Worldwide LLC
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Contact Person:

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Date Prepared: April 25, 2016

II. DEVICE

Name of Device: MENTOR® ARTOURA™ Breast Tissue Expanders with Smooth Surface

Common Device Name: Expander, Skin, Inflatable

Classification Regulation: Unclassified, Pre-Amendment

Panel: General & Plastic Surgery

Product Code: LCJ

III. PREDICATE DEVICE

K150777, MENTOR® ARTOURA™ Breast Tissue Expanders

This predicate has not been subjected to a design-related recall or any type of any recall.

IV. DEVICE DESCRIPTION

MENTOR® ARTOURA™ Breast Tissue Expanders with Smooth Surface consist of a silicone elastomer shell, with interior structural elements to allow 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 MENTOR® ARTOURA™ Breast 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 MENTOR® ARTOURA™ Breast Tissue Expanders with Smooth Surface are provided sterile in two styles (High and Ultra High) and various sizes.

The following accessories are packaged with the MENTOR® ARTOURA™ Breast Tissue Expanders with Smooth Surface:

- Centerscope Magnetic Injection Port Finder
- Winged Infusion Set

V. INDICATIONS FOR USE

MENTOR® ARTOURA™ 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.

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® ARTOURA™ Breast Tissue Expanders (K150777).

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. ARTOURA™ Breast Tissue Expanders and ARTOURA™ Breast Tissue Expanders with Smooth Surface devices will be manufactured with identical components, however the ARTOURA™ Tissue Expanders with Smooth Surface will have a smooth exterior surface while the predicate device has a textured exterior surface. All other device features and specifications remain unchanged. The brand name of the proposed device is MENTOR® ARTOURA™ Breast 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 ARTOURA™ Tissue Expanders with Smooth Surface will have a smooth outer surface and a textured inner surface (reverse shell configuration as compared to the predicate device), the connection of the internal and external components relative to the shell surface will change. .

Testing performed evaluated parameters related to joint strength of affected joints 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:

MENTOR® ARTOURA™ Breast Tissue Expander with Smooth Surface is an implantable device, the contact category according to ISO 10993-1 is: Implant, tissue contacting, permanent (> 30 days). All materials used in the ARTOURA™ Breast Tissue Expander 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® ARTOURA™ Breast Tissue Expanders with Smooth Surface are substantially equivalent to the predicate device, MENTOR® ARTOURA™ Breast Tissue Expander (K150777). MENTOR® ARTOURA™ 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 ARTOURA™ Breast Tissue Expanders (predicate device). Performance evaluations demonstrate that the subject device is as safe and effective as the predicate device. MENTOR® ARTOURA™ Breast Tissue Expanders with Smooth Surface are therefore substantially equivalent to the ARTOURA™ Breast Tissue Expanders (predicate device).