



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

April 24, 2015

Mentor Worldwide LLC  
Manchi Cheung  
Regulatory Manager  
201 Mentor Drive  
Santa Barbara, California 93111

Re: K150777

Trade/Device Name: Artoura™ Breast Tissue Expanders  
Regulatory Class: Unclassified  
Product Code: LCJ  
Dated: March 25, 2015  
Received: March 26, 2015

Dear Cheung:

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" (21CFR 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,

**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

## Indications for Use

510(k) Number (if known)

K150777

Device Name

Artoura (TM) Breast Tissue Expanders

Indications for Use (Describe)

The Artoura (TM) Breast Tissue Expanders 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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

### FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@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.”*

## **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 is provided below.

### **I. SUBMITTER**

Mentor Worldwide LLC  
201 Mentor Drive  
Santa Barbara, CA 93111

Contact Person:  
Manchi Cheung  
Regulatory Manager  
Phone: 805 -879-6790  
Fax: 805-879-6167  
[mcheung3@its.jnj.com](mailto:mcheung3@its.jnj.com)

Date Prepared: March 24, 2015

### **II. DEVICE**

**510 (k) Number:** K150777

**Name of Device:** Mentor Artoura® Breast Tissue Expanders

**Common Device Name:** Expander, Skin, Inflatable

**Classification**

**Regulation:** Unclassified, Pre-Amendment

**Panel:** General & Plastic Surgery

**Product Code:** LCJ

### **III. PREDICATE DEVICE**

K142998, Mentor® CPX™ Control Breast Tissue Expanders  
This predicate has not been subjected to a design-related recall.

### **IV. DEVICE DESCRIPTION**

The Mentor® Artoura™ Breast Tissue Expander consists 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 Expander incorporates suture tabs to provide surgeons with the option to attach the device to surrounding tissue for enhanced device stability.

The Mentor® Artoura™ devices are provided sterile in various styles and sizes.

The following accessories are packaged with the Artoura™ Tissue Expander:

- Centerscope Magnetic Injection Port Finder
- Winged Infusion Set

## **V. INDICATIONS FOR USE**

The Mentor® Artoura™ Breast Tissue Expander 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 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™ Control Breast Tissue Expander (K142998)

This 510 (k) pre-market notification describe changes to the predicate's device size and dimensions. All other components, device features and specifications remain unchanged. In addition, the brand name of the device is being updated to Artoura™ Breast Tissue Expander.

## **VII. PERFORMANCE DATA**

Biocompatibility Testing:

The Mentor® Artoura™ Breast Tissue Expander is an implantable device, the contact category according to ISO10993-1 is: Implant, tissue contacting, permanent (> 30 days). All materials used in the Artoura™ tissue expander are identical to the materials used in the predicate device.

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 joint strength, leak performance and other performance characteristics

in accordance with ASTM F1441-03, Standard Specification for Soft-Tissue Expanders.

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 Mentor® Artoura™ Breast Tissue Expander is substantially equivalent to the predicate device, Mentor® CPX™ Control Breast Tissue Expander (K142998). The Artoura® Breast Tissue Expander has the same indications for use, operating principle and technological characteristics as the predicate device. Performance evaluations demonstrate that the subject device is substantially equivalent to the predicate device.