



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

May 20, 2015

Mentor Worldwide LLC  
Ms. Sarah McManus  
Associate Director, Regulatory Affairs  
201 Mentor Drive  
Santa Barbara, California 93111

Re: K151055

Trade/Device Name: MENTOR MemoryShape Resterilizable Gel Breast Implant  
Sizer STERILE

Regulatory Class: Unclassified

Product Code: MRD

Dated: April 17, 2015

Received: April 20, 2015

Dear Ms. McManus:

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)

K151055

Device Name

MENTOR MemoryShape Resterilizable Gel Breast Implant Sizer STERILE

Indications for Use (Describe)

The MENTOR MemoryShape Resterilizable Gel Breast Implant Sizer is indicated for temporary insertion intraoperatively to evaluate the size and shape of the MemoryShape breast implant to be implanted.

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 OF SAFETY AND EFFECTIVENESS INFORMATION**

**Sponsor:** Mentor Worldwide, LLC.  
201 Mentor Drive  
Santa Barbara, CA 93111

**Contact:** Sarah McManus  
Associate Director Regulatory Affairs  
Phone: 908-218-2954  
Fax: 908-218-2595  
Email: [smcmanu3@its.jnj.com](mailto:smcmanu3@its.jnj.com)

**Date of Submission:** 17 April 2015

**Proprietary Name:** MENTOR® MemoryShape™ Resterilizable Gel Breast Implant Sizer  
STERILE

**Common Name:** Sizer, Mammary, Breast Implant Volume

**Regulation:** Unclassified, pre-amendment

**Regulatory Class:** Unclassified

**Product Code:** MRD

**Predicate Device:** MENTOR® MemoryShape™ Resterilizable Gel Breast Implant Sizer  
(K131853)

**Device Description:** The MENTOR® MemoryShape™ Resterilizable Gel Breast Implant Sizer STERILE (Gel Sizer) is designed for temporary intra-operative placement in the surgically prepared breast pocket. The Gel Sizer is used to evaluate the appropriate breast implant size and shape for each patient prior to implantation of a MemoryShape™ (contour shape) breast implant. The Gel Sizer is provided sterile and can be used out of the box for the initial use. The Gel Sizer is then resterilized 9 additional times for a total of 10 uses. The MemoryShape™ sizers are offered in various sizes to match the corresponding MemoryShape™ breast implants. These gel sizers contain raised orientation marks on the anterior and posterior of the device to help the physician with placement.

**Indications for Use:** The MENTOR® MemoryShape™ Resterilizable Gel Breast Implant Sizer is indicated for temporary insertion intra-operatively to evaluate the size and shape of the MemoryShape™ breast implant to be implanted.

---

**Technological Characteristics:** The proposed device, MENTOR® MemoryShape™ Resterilizable Gel Breast Implant Sizer STERILE, and the predicate device, MENTOR® MemoryShape™ Resterilizable Gel Breast Implant Sizer, are made of the same materials, are made with the same component parts, and are offered in the same range of styles, dimensions, and fill volume. Both the proposed device and the predicate device can be used a total of 10 times.

The proposed device is provided sterile and can be used out of the box for the initial use, while the predicate device is provided non-sterile and must be sterilized prior to initial use. For all subsequent uses, both devices must be cleaned and sterilized prior to use.

The proposed device is packaged in sterile barrier packaging and has a shelf life of five (5) years.

**Performance Data:** Non-clinical performance testing was conducted in order to demonstrate substantial equivalence with the predicate device. The testing that was performed is summarized as follows:

- x Elongation
- x Tension Set
- x Break Force
- x Patch to Shell Joint Testing
- x Gel Cohesion

All non-clinical performance testing results met their pre-determined acceptance criteria, thus demonstrating that the modified device is substantially equivalent to the predicate device. In addition, stability, sterilization, and packaging data demonstrate that the changes to the device do not raise different questions of safety or effectiveness.

**Conclusions:** The proposed device, MENTOR® MemoryShape™ Resterilizable Gel Breast Implant Sizer STERILE, is substantially equivalent to the predicate device, MENTOR® MemoryShape™ Resterilizable Gel Breast Implant Sizer. There have been no changes to the intended use and indications for use. The device materials, component parts, dimensions, styles, and volumes remain unchanged.

The changes to the device do not raise different questions of safety or effectiveness. Results of non-clinical performance evaluations demonstrate that the proposed device is substantially equivalent to the predicate device.

---