K131853

5.0 510(k) Summary

JUL 17 2013

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the Mentor MemoryShape™ Resterilizable Gel Sizer device is provided below.

Device Common Name: Sizer, Mammary, Breast Implant Volume

Device Proprietary Name: Mentor MemoryShape™ Resterilizable Gel Sizer

Submitter:
MENTOR Worldwide LLC
201 Mentor Drive
Santa Barbara, CA 93111

Contact:
Manchi Cheung
Regulatory Project Manager
201 Mentor Dr.
Santa Barbara, CA 93111
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Date Prepared: June 20, 2013

Classification Regulation: Unclassified, Pre-Amendment

Panel: General & Plastic Surgery

Product Code: MRD

Predicate Device: K062421, Mentor Resterilizable Gel Breast Implant Sizer

Indication for Use:
The Mentor Resterilizable MemoryShape™ Gel Sizer is indicated for temporary insertion intra-operatively to evaluate the size and shape of the MemoryShape™ breast implant to be implanted.

Device Description:
The Mentor Resterilizable MemoryShape™ Gel Breast Implant Sizer (Gel Sizer) is designed for temporary intraoperative 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 non-sterile to be sterilized prior to initial use and 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.

Technological Characteristics

The proposed modifications to the already cleared Mentor Resterilizable Gel Sizer include minor configuration changes to device shape and volume, gel fill, and addition of orientation marks. No new technological characteristics were introduced as a result of the proposed modifications.

Performance Data:

Non-clinical performance testing was conducted 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 that was performed is summarized as follows:

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

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.

Substantial Equivalence:

This 510(k) describes minor changes to the design of the Mentor Resterilizable Gel Breast Implant Sizer. There have been no changes to the indications for use or the intended use. The changes do not raise different questions of safety or effectiveness and results of non-clinical performance evaluations demonstrate that the proposed device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 17, 2013

Mentor Worldwide LLC
% Ms. Manchi Cheung
Regulatory Project Manager
201 Mentor Drive
Santa Barbara, California 93111

Re: K131853
Trade/Device Name: Mentor MemoryShape™ Resterilizable Gel Breast Implant Sizer
Regulatory Class: Unclassified
Product Code: MRD
Dated: June 20, 2013
Received: June 21, 2013

Dear Ms. 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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

FOR Peter D. Rumm -S

Mark N. Melkerson, M.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.0 Indications for Use Statement

510(k) Number (if known): K131853

Device Name:
Mentor Resterilizable MemoryShape™ Gel Breast Implant Sizer

Indications For Use:

The Mentor Resterilizable MemoryShape™ 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.

Prescription Use __X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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David Krause -S

K131853

(Division Sign-Off)
Division of Surgical Devices
510(k) Number K131853