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This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92

The assigned 510(k) number is: K062421

OCT 10 2006

Contact Person: Nicola Selley
Senior Director, Clinical and Regulatory Affairs
Mentor Corporation
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Date Prepared:

Device Name and Classification

Trade Name: Mentor Resterilizable Gel Breast Implant Sizer

Common Name: Volume Sizer for Breast Implants

Classification Name: Not Classified

Product Code: MRD

Manufacturer

Mentor Texas
3041 Skyway Circle North
Irving, TX 75038

Device Description

The Mentor Resterilizable Gel Breast Implant Sizer (Sizer) is a silicone elastomer device, filled with silicone gel, that is designed for temporary intraoperative placement in the surgically prepared breast pocket. The Sizer is used to evaluate the appropriate MemoryGel™ breast implant size and shape for each patient prior to implantation of a breast implant. It is provided non-sterile and must be sterilized prior to use. The Sizer should not be sterilized more than ten times.

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Substantial Equivalence Claim

The Mentor Resterilizable Sizer is substantially equivalent to the Mentor Sterile Saline Sizer which received clearance under 510(k) K010709. The primary differences are that the Mentor Sterile Saline Sizer is provided sterile, for one time use only, and is filled with saline. The Mentor Resterilizable Gel Sizer is provided non-sterile, can be resterilized and reused up to ten times, and is filled with silicone gel.

Indications for Use

The Mentor Restelizable Gel Breast Implant Sizer is indicated for temporary insertion intraoperatively to evaluate the size and shape of the MemoryGel™ breast implant to be implanted.

Summary of Testing

The materials being used in the Sizer were tested for biological safety. All materials passed the requirements of ISO 10993 for biocompatibility.

A design verification study was performed to assess the physical properties of the Sizers after ten cleanings, sterilizations, and insertions. All physical characteristics passed the acceptance criteria as defined in the protocol. These results confirmed that the Sizer met the design specifications after ten cleanings, sterilizations and insertions.

A qualification of the cleaning and sterilization procedures as recommended in the labeling was performed. The results of this qualification provide documented evidence that Mentor's cleaning and sterilization procedures as recommended in the labeling achieve a minimum sterility assurance level of $10^{-6}$.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 10 2006

Mentor Corporation
% Ms. Nicola Selley
Sr. Director, Clinical & Regulatory
Affairs
201 Mentor Drive
Santa Barbara, California 93111

Re: K062421
Trade/Device Name: Mentor Resterilizable Gel Breast Implant Sizer
Regulatory Class: Unclassified
Product Code: MRD
Dated: August 16, 2006
Received: August 22, 2006

Dear Ms. Selley:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Barbara Bucher

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K062421

Device Name:

Mentor Resterilizable Gel Breast Implant Sizer

Indications For Use:

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

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

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buehler MD

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K062421