September 6, 2024

Mentor Worldwide LLC
Alicia Botham
Senior Program Lead
31 Technology Drive
Irvine, California 92614

Re: K241552
Trade/Device Name: MENTOR™ MemoryGel™ Enhance Single Use Gel Sizer
Regulatory Class: Unclassified
Product Code: MRD
Dated: May 24, 2024
Received: May 31, 2024

Dear Alicia Botham:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Alicia Hemphill -S Digitally signed by Alicia Hemphill -S
Date: 2024.09.06 21:10:36 -05'00'

Alicia Hemphill
Assistant Director
DHT4B: Division of Plastic and
Reconstructive Surgery Devices
OHT4: Office of Surgical and
Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241552

Device Name
MENTOR™ MemoryGel™ Enhance Single Use Gel Sizer

Indications for Use *(Describe)*
The MENTOR MemoryGel™ Enhance Single Use Gel Breast Implant Sizer is indicated for single use only for temporary insertion intraoperatively to evaluate the shape and size of the MemoryGel™ Enhance 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)

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
(K241552)

Contact Person: Alicia Botham
Senior Program Lead, Regulatory Affairs
Mentor Worldwide LLC
31 Technology Drive
Irvine, CA 92618

Telephone: 828-775-0302

Email: ABotham1@its.jnj.com

Date Prepared: May 31, 2024

Device Name and Classification

Trade Name	MENTOR™ MemoryGel™ Enhance Single Use Gel Sizer
Common Name	Volume Sizer for Breast Implants
Product Code	MRD – Mammary Sizer
Device Classification Regulation	Unclassified, Pre-Amendment
Classification Panel	General and Plastic Surgery
Premarket Review	Office of Health Technology 4 (Surgical and Infection Control Devices) Division of Health Technology 4B (Infection Control and Plastic and Reconstructive Surgery)

Predicate Device

MENTOR™ MemoryGel™ Resterilizable Gel Sizer, K062421

This predicate has not been subject to a design-related recall.

Device Description

The MENTOR™ MemoryGel™ Enhance Single Use 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 sterile and is for single use only. The Sizer should not be resterilized.

Indications for Use

The MENTOR™ MemoryGel™ Enhance Single Use Gel Breast Implant Sizer is indicated for single use only for temporary insertion intraoperatively to evaluate the size and shape of the MemoryGel™ Enhance Breast Implant to be implanted.

Comparison of Technological Characteristics with the Predicate Device:

The MENTOR™ MemoryGel™ Enhance (SZUHE) Single Use Gel Sizer is substantially equivalent to the MENTOR™ Resterilizable Gel Sizer which received clearance under 510(k) K062421. The primary differences are the Mentor Resterilizable Gel Sizer is provided non-sterile, can be resterilized and reused up to ten times. The MENTOR™ MemoryGel™ Enhance Gel Breast Implant Sizer is provided sterile and is for single use only.

	MENTOR™ MemoryGel™ Enhance Single Use Gel Sizer (under review)	**Mentor Resterilizable Gel Sizer 510(k) K062421**
Indication for Use	The Sizer is only indicated for single use for temporary insertion intraoperatively to evaluate the size and shape of the MemoryGel™ Enhance Breast Implant to be implanted.	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.
Shell	Polydimethylsiloxane and Phenyl Polydimethylsiloxane (Low Bleed Layer) Heat Cured	Polydimethylsiloxane and Phenyl Polydimethylsiloxane (Low Bleed Layer) Heat Cured
Low Bleed Patch	Polydimethylsiloxane Phenyl Polydimethylsiloxane (Low Bleed Layer) Heat Cured	Polydimethylsiloxane Phenyl Polydimethylsiloxane (Low Bleed Layer) Heat Cured
Pad Printing	Polydimethylsiloxane Moisture Cured	Polydimethylsiloxane Moisture Cured

Filler	Silicone Gel (prefilled)	Silicone Gel (prefilled)
Sterilization	Provided Sterile (Dry Heat)	Provided Non-sterile (with cleaning and sterilization instructions)
Use	Single Use Only	Up to 10 times use

Device Component Comparison for Predicate and Proposed Device(s)

Component	**MENTOR™ MemoryGel™ MC, M+, HP, UHP Resterilizable Gel Breast Implant Sizer** **(Predicate)**	**MENTOR™ MemoryGel™ Enhance Single Use Gel Sizer** **(Proposed)**	**Patient Contacting**
Silicone Shell	Polydimethylsiloxane Dimethyl: MED-6649 Diphenyl: MED-6609	Same as predicate	Yes
Silicone gel	1 Part Pre-Mix Restricted Gel: GEL1-8109	Nusil MED3-6300-1 Unrestricted Gel	No
Low Bleed Patch	Polydimethylsiloxane Dimethyl: MED-6649 Diphenyl: MED-6609	Same as predicate	No
Patch Disk	MED-4735	Same as predicate	No
Disk	MED-4735	Same as predicate	No
Dip Coat	Dow Corning 92-009	Same as predicate	Yes
Black Silicone Ink	Silicone CF3-1008-2	Same as predicate	Yes
Shell Thickness	Minimum thickness is 0.009”	Same as predicate	N/A

Summary of Non-Clinical Testing:

Biocompatibility

The MENTOR™ MemoryGel™ Enhance Single Use Gel Sizer is currently categorized as a limited (<24hrs) tissue contacting device as per EN ISO 10993-1 (2020) and FDA Guidance for Industry “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"

(2023). The materials being used in the Sizer were tested for biological safety. All materials passed the requirements of ISO 10993 for biocompatibility.

The device was first qualified as a breast implant and therefore, testing conducted to qualify the device as an implant can be applied to the device used as a sizer. Per the Design Verification Plan, the only difference between the device as an implant the device as a sizer (the subject of this application), is device labelling as well as pad printing to read "SINGLE USE ONLY" and "NOT FOR IMPLANT."

Summary of Toxicology and Biocompatibility Testing & Results Considered for the MENTOR™ MemoryGel™ Enhance Single Use Gel Sizer

Test	Test Article	Results
Cytotoxicity Study (ISO Agarose Overlay and ISO Elution)	Intact, smooth and Siltex MemoryGel breast implants	Passed
Sensitization (Maximization Method)	MemoryGel smooth shell, textured shell and silicone gel	Passed
Intracutaneous Reactivity	Smooth and Siltex MemoryGel breast implants	Passed
Acute Systemic Toxicity	Smooth and Siltex MemoryGel breast implants	Passed
Hemocompatibility (Direct Contact and Extraction)	Siltex and smooth MemoryGel breast implants	Passed
Pyrogenicity – Material Mediated	Smooth and Siltex MemoryGel breast implants	Non-pyrogenic.
Pyrogenicity – Limulus Amebocyte Lysate (LAL)	Smooth MemoryGel Breast Implants	Non-pyrogenic
Genotoxicity - Bacterial Reverse Mutation Assay	Smooth MemoryGel breast implant	Negative for genotoxic activity
Genotoxicity - Unscheduled DNA Synthesis Assay in Mammalian Cells *In Vitro*	Smooth MemoryGel breast implant	Negative for genotoxic activity
Genotoxicity - Chromosome Aberrations in Chinese Hamster Ovary (CHO) Cells	Smooth MemoryGel breast implant	Negative for genotoxic activity
Genotoxicity - Micronucleus Cytogenetic Assay in Mice	Siltex MemoryGel breast implant	Negative for genotoxic activity
Implantation	Siltex MemoryGel Breast Implant	Non-irritating
Immunotoxicity	Smooth and Siltex MemoryGel breast implants	No significant effects of the test articles on the immunological response

Autoantibody Production	Smooth MemoryGel Breast Implant Shell	No significant differences were found for the serum IFN-γ levels among the treatment groups of this experiment.
Adjuvancy	Siltex MemoryGel Breast Implant Shell and Gel	Unlikely that silicone gels cause an adjuvant effect in humans
Reproductive Toxicity/Teratogenicity	Smooth MemoryGel Breast Implant Shell, Siltex MemoryGel Breast Implant Shell and Gel	Did not cause reproductive or terotogenic effects
Chronic Toxicity/Carcinogenicity	Smooth MemoryGel Breast Implant Shell, Siltex MemoryGel Breast Implant Shell and Gel	Not considered to be carcinogenic

Performance Data

Mentor conducted design verification to assess the physical properties of the Sizers, which leverages the testing conducted to qualify the device as an implant. The following tests were performed: Shell/Patch Joint Strength, Shell Elongation, Shell Tension Set, Shell Break Force, and Gel Cohesiveness. In addition, Bioburden Testing and Routine LAL Testing were conducted to verify device microbiological safety. All physical characteristics passed the acceptance criteria as defined in the protocol. These results confirm that the device meets implant design specifications, and therefore qualifies the device to be used as a sizer for temporary intraoperative use by means of substantial equivalence to the predicate device.

Summary and Conclusion

The combination of successful performance testing (passing all acceptance criteria), unchanged indications for use, and unchanged technological characteristics, demonstrate substantial equivalence of the proposed device to the predicate device. The conclusions drawn from the nonclinical testing (discussed above) demonstrate that the subject device (K241552) is as safe, as effective and performs as well as or better than the predicate device (MENTOR™ Resterilizable Gel Breast Implant Sizer, K062421).