January 13, 2025

Mentor Worldwide, LLC
Saakshi Arora-Tice
Senior Regulatory Affairs Program Lead
31 Technology Drive
Irvine, California 92614

Re: K243271
Trade/Device Name: MENTOR™ MemoryShape™ Resterilizable Gel Breast Implant Sizer; MENTOR™ MemoryGel™ Resterilizable Gel Breast Implant Sizer; MENTOR™ MemoryGel™ Enhance Single Use Gel Sizer
Regulatory Class: Unclassified
Product Code: MRD
Dated: November 14, 2024
Received: November 14, 2024

Dear Saakshi Arora-Tice:

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: 2025.01.13 12:11:08 -06'00'

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.*

Submission Number *(if known)*

K243271

Device Name

MENTOR™ MemoryShape™ Resterilizable Gel Breast Implant Sizer;
MENTOR™ MemoryGel™ Resterilizable Gel Breast Implant Sizer;
MENTOR™ MemoryGel™ Enhance Single Use Gel Sizer

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.

The MENTOR™ MemoryGel™ 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.

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.**

**510(k) Summary**
**(K243271)**

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Telephone: 908-707-3561

Email: sarorati@its.jnj.com


Date Prepared: January 8, 2025

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Device Name and Classification

| | |
|---|---|
| Trade Name | MENTOR™ MemoryShape™ Resterilizable Gel Breast Implant Sizer (K131853)<br>MENTOR™ MemoryGel™ Resterilizable Gel Breast Implant Sizer (K151055)<br>MENTOR™ MemoryGel™ Enhance Single Use Gel Sizer (K241552) |
| Common Name | Volume Sizer for Breast Implants |
| Product Code | MRD |
| Device Classification Regulation | Unclassified, Pre-Amendment |
| Classification Panel | General and Plastic Surgery |
| Premarket Review | Office of Health Technology 4 (Surgical and Infection Control Devices)<br>Division of Health Technology 4B (Infection Control and Plastic and Reconstructive Surgery) |

Predicate Device

The predicate device referenced in this submission is the previously cleared device that utilized the original dip coat material. The devices have the same technological characteristics as the predicate device(s). The only difference is the Dip Coat component which is changing from Krayden / Dow DC 92-009 to NuSil MED6-6605 material on all Sizers manufactured at the MENTOR™ Texas.

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.

The MENTOR™ Resterilizable Gel Breast Implant Sizer (Sizer) is a silicone elastomer device, filled with silicone gel, that is designed for temporary intra-operative 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.

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 intra operative 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™ 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.

The MENTOR™ MemoryGel™ 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.

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.

Comparison of Technological Characteristics with the Predicate Device

MENTOR™ is changing the current material for the Dip Coat component from Krayden / Dow DC 92-009 to NuSil™'s MED6-6605 material on all Gel Implants and Sizers manufactured at the MENTOR™ Texas. The table below compares the current Dip Coat DC 92-009 from Krayden/Dow Corning and the proposed material MED6-6605 from Nusil™. The devices have the same technological characteristics as the predicate device(s). The only difference is the Dip Coat component which is changing from Krayden / Dow DC 92-009 to NuSil MED6-6605 material on all Sizers manufactured at the MENTOR™ Texas.

**Table 1: Comparison of Technological Characteristics with the Predicate Device**

<table>
<tr><th>Characteristic</th><th>Description</th><th>From (Gel Sizers current design/state)</th><th>To (Gel Sizers proposed design/state)</th></tr>
<tr><td>Indications for Use</td><td>Indications for Use</td><td>a) MENTOR™ MemoryShape™ Resterilizable Gel Breast Implant Sizer<br>The Gel Sizer is indicated for use for temporary insertion intra-operatively to evaluate the size and shape of the MemoryShape™ Breast Implant to be implanted.<br><br>b) MENTOR™ MemoryGel™ Resterilizable Gel Breast Implant Sizer<br>The Sizer is indicated for temporary insertion intraoperatively to evaluate the size and shape of the MemoryGel™ breast implant to be implanted.<br><br>c) MENTOR™ MemoryGel™ Enhance Singe Use Gel Sizer<br>The Sizer is indicated for temporary insertion intraoperatively to evaluate the size and shape of the MemoryGel™ Enhance Breast Implant to be implanted. Prior to using the Gel Sizer, the physician should be familiar with all the literature associated with the MemoryGel™ Enhance Breast Implant to be implanted.</td><td>No Change</td></tr>
<tr><td rowspan="6">Sterilization</td><td rowspan="6">Dry Heat Sterilization</td><td colspan="2">MENTOR™ MemoryShape™ Resterilizable Gel Breast Implant Sizer, MENTOR™ MemoryGel™ Resterilizable Gel Breast Implant Sizer</td></tr>
<tr><td>Temp: 236ºF Min/ 251ºF Max</td><td>No Change</td></tr>
<tr><td>Time: 34 hrs. Min/ 38 hrs. Max</td><td>No Change</td></tr>
<tr><td colspan="2">MENTOR™ MemoryGel™ Enhance Singe Use Gel Sizer</td></tr>
<tr><td>Temp: 236ºF Min/ 251ºF Max</td><td>No Change</td></tr>
<tr><td>Time: 48 hrs. Min/ 52 hrs. Max</td><td>No Change</td></tr>
<tr><td>Material</td><td>RTV Dispersion Coating</td><td>Supplier: Krayden/Dow Corning<br>Materials: DC 92-009</td><td>Supplier: NuSil™<br>Materials: MED6-6605</td></tr>
</table>

| Characteristic | Description | From (Gel Sizers current design/state) | To (Gel Sizers proposed design/state) |
|---|---|---|---|
| | Device Contact Materials for Dip Coat Applied to Outside Surface of TX Devices | Patch Disk<br>Materials: MED4735 | No Change |
| | | Patch Fill- Reinforced<br>Materials: MED4750 Silicone | No Change |
| | | Silicone Gel (MemoryShape Family)<br>Materials: MED3-6309-1, Cohesive III (1:1 Mixed Gel) | No Change |
| | | Silicone Gel (MemoryGel Family)<br>Materials: GEL1-8109, 1-Part Pre-Mix Gel | No Change |
| | Indirect / Non-contact TX Device Materials with Dip Coat | Shell<br>Material: MED-6649 (Dimethyl), MED-6609 (Diphenyl) | No Change |
| | | Low Bleed Patch<br>Material: MED-6649 (Dimethyl), MED-6609 (Diphenyl) | No Change |

Summary of Non-Clinical Testing

Biocompatibility

MENTOR™ has completed a Biological Evaluation Matrix (BEM) focusing on a proposed material change and identifies and characterizes the materials based on their type and the duration of patient contact. The Dip Coat has direct patient contact for either a limited duration (≤ 24 hours) for sizers or long-term (>30 days) for implants. Regardless of the device's size, all devices use about the same amount (1-2 drops, <0.02 grams) of Dip Coat material. The proposed alternative is NuSil™ MED6-6605 - RTV Silicone, which is already used in other MENTOR™ Saline-Filled and Spectrum Adjustable Breast Implants and Saline Sizers. These implants were first approved by the US FDA on May 10, 2000 (PMA Number P990075) and are marketed outside the US (CE mark in 1995) with no significant safety issues related to the silicone.

MENTOR™ has also conducted a Biocompatibility and Toxicology Risk assessment for the proposed sizer devices dip coated with MED6-6605. The proposed dip coat material MED6-6605 is already used in other MENTOR™ Saline-Filled and Spectrum Adjustable Breast Implants and Saline Sizers. A detailed biocompatibility risk assessment was conducted on these devices which concluded that these devices present no significant biocompatibility risk when used as long-term implants or limited-duration sizers. Based on existing chemical, biological data and history of clinical use, Spectrum and Saline filled Breast Implants and Sizers present no significant risk of adverse biologic reactions in patients.

Table 2 provides a summary of the biological tests of the dipcoat material (MED6-6605) which is already used in MENTOR™ saline-filled implants and sizers (P990075). Table 3 provides a summary of the biological tests of the sizer (other than dipcoat material).

**Table 2: Summary of Toxicology and Biocompatibility Testing & Results Applicable to Dip Coat as used in MemoryGel, MemoryShape & MemoryGel Enhance Sizers**

| Test | Test Article | Result |
|---|---|---|
| Cytotoxicity, Elution | MENTOR™ Saline-Filled and Spectrum™ Mammary Prostheses (Device – cut samples) | No evidence of cell lysis or toxicity |
| Cytotoxicity, Direct | MENTOR™ Saline-Filled and Spectrum™ Mammary Prostheses (Shell - outside surface) | Slight evidence of cell lysis and toxicity |
| Sensitization | MENTOR™ Saline-Filled and Spectrum™ Mammary Prostheses (Shell) | No evidence of sensitization |
| Irritation/ Intracutaneous Reactivity | MENTOR™ Saline-Filled and Spectrum™ Mammary Prostheses (Device – cut samples) | No evidence of irritation |
| Pyrogenicity, Material-mediated pyrogenicity | MENTOR™ Saline-Filled and Spectrum™ Mammary Prostheses (Device – cut samples) | Non-pyrogenic |
| Acute Systemic Toxicity | MENTOR™ Saline-Filled and Spectrum™ Mammary Prostheses (Device – cut samples) | No evidence of systemic toxicity |

**Table 3: Summary of Toxicology and Biocompatibility Testing & Results Conducted for Gel Breast Implant Sizers**

| Test | Test Article | Result |
|---|---|---|
| Cytotoxicity - Elution | MENTOR™ MemoryGel™ Resterilizable Gel Breast Implant Sizer | No evidence of cell lysis or toxicity |
| Sensitization | MENTOR™ MemoryGel™ Resterilizable Gel Breast Implant Sizer | No evidence of sensitization |
| Irritation/ Intracutaneous Reactivity | MENTOR™ MemoryGel™ Resterilizable Gel Breast Implant Sizer | No evidence of irritation for SC extract Slight edema/erythema for SO extract Primary Irritation Index was negligible |
| Material mediated pyrogenicity | MENTOR™ MemoryGel™ Resterilizable Gel Breast Implant Sizer | Non-pyrogenic |
| Acute Systemic Toxicity | MENTOR™ MemoryGel™ Resterilizable Gel Breast Implant Sizer | No mortality or evidence of systemic toxicity |
| Endotoxin Mediated pyrogenicity | MENTOR™ MemoryGel™ Resterilizable Gel Breast Implant Sizer<br>MENTOR™ MemoryShape™ Resterilizable Gel Breast Implant Sizer | Non-pyrogenic: all lots passed |

Performance Data

MENTOR™ has completed the performance qualification (PQ) for the use of the alternate MED6-6605 for the Dip Coat application process located in MENTOR™ Irving, Texas Site. The PQ acceptance criteria defined in the PQ Protocol were satisfactorily met (see Table 4).

**Table 4: Summary of testing and conclusions of the Dip Coat Process PQ Testing**

| Attribute Requirement | Acceptance Criteria | PASS/FAIL & Result / Conclusion |
|---|---|---|
| In Process Visual Inspection | Yield ≥ Product Target Yield | **PASS**<br>In Process Visual inspection on each of the lots showed a Yield above the Product Target Yield |
| Visual Inspection after 2X Sterilization Process | C=0 / 100% Pass | **PASS**<br>Visual inspection after 2X Sterilization Process showed 100% acceptable Dip Coat. |

As a result of this qualification activity, it is concluded that the Dip Coat process using MED6-6605 has successfully passed PQ activities based on the acceptance criteria. This PQ established with objective evidence the Dip Coat Process, under anticipated conditions, can consistently produce products that meet all predetermined requirements. Based on the satisfactory results, it can be concluded that alternate material MED6-6605 is suitable material for Dip Coat application and can be released for commercial manufacturing once the regulatory approvals are obtained.

MENTOR™ has conducted Sizers Reprocessing Product Lifetime testing to verify that MED6-6605 (NuSil™ Technology) can adequately function as a suitable Dip Coat material and perform as intended over the product lifetime of MENTOR™ gel sizers manufactured at MENTOR™ Texas. Based on the satisfactory results (see Table 5), it can be concluded that alternate material MED6-6605 functioned as a suitable dispersion coating (dip coat) material over the expected product lifetime of MENTOR™ gel sizers manufactured by MENTOR™ Texas.

**Table 5: Summary of testing and conclusions of the Sizers Reprocessing Product Lifetime testing**

| Criteria for Success Requirements | Acceptance Criteria | Test Results (PASS/FAIL)? |
|---|---|---|
| Visual examination | The dip coat on each device shall maintain full integrity and adherence of the dipcoat to the substrate posterior side of the sizer. | **PASS** |
| | There shall be no evidence of leakage of gel or like fluid in and around the dip coat at the injection hole site. | **PASS** |
| | Dip coat shall show no sign of cracking, delamination, or any leakage from fill hole. | **PASS** |

There was no evidence of dip coat failure, nor were any leakages detected at the dip coat injection site of any of the test samples. Therefore, MED6-6605 successfully functioned as a suitable

dispersion coating (dip coat) material over the expected product lifetime of MENTOR™ gel sizers manufactured by MENTOR™ Texas.

Summary and Conclusion

The combination of successful performance testing (passing all acceptance criteria), biocompatibility, unchanged indications for use, and unchanged technological characteristics, demonstrate substantial equivalence of the proposed devices to the predicate devices. The conclusions drawn from the nonclinical testing (discussed above) demonstrate that the proposed sizer devices dip coated with MED6-6605 from Nusil™ is as safe, as effective and performs as well as the predicate devices dip coated with DC 92-009 from Krayden/ Dow.