February 5, 2019

Motiva USA, LLC
% Michael Billig
Chief Executive Officer
Experien Group, LLC
224 Airport Parkway, Suite 250
San Jose, California 95110

Re: K183163
Trade/Device Name: Intraoperative, Single-Use, Sterile, Silicone Breast Sizer Motiva Implant Matrix
Regulatory Class: Unclassified
Product Code: MRD
Dated: November 14, 2018
Received: November 15, 2018

Dear Michael Billig:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Krause -S

Digitally signed by David Krause -S
Date: 2019.02.05 08:16:22 -05'00'

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183163

Device Name
Intraoperative, Single-Use, Sterile, Silicone Breast Sizer Motiva Implant Matrix

Indications for Use *(Describe)*
Intraoperative, Single-use, Sterile, Silicone Breast Sizers Motiva Implant Matrix are temporary intraoperative placement devices used during breast augmentation or reconstruction procedures to assist the surgeon in determining the appropriate size of the long-term breast implant to use.

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.

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510(k) Notification K183163

GENERAL INFORMATION [807.92(a)(1)]

Applicant:

Motiva USA LLC
712 Fifth Avenue, 14th Floor
New York, NY 10019-4108 USA
Phone: 888-846-2915

Contact Person:

Michael J. Billig
Chief Executive Officer
Experien Group, LLC
224 Airport Parkway, Suite 250
San Jose, CA 95110 USA
Phone: 408-400-0856
FAX: 408-400-0865

Date Prepared: January 30, 2019

DEVICE INFORMATION [807.92(a)(2)]

Trade Name:

Intraoperative, Single-Use, Sterile, Silicone Breast Sizers Motiva Implant Matrix®

Generic/Common Name:

Sizer, Mammary, Breast Implant

Classification:

Unclassified

Product Code:

MRD

PREDICATE DEVICE(S) [807.92(A)(3)]

Motiva USA asserts that the Intraoperative, Single-use, Sterile, Silicone Breast Sizers Motiva Implant Matrix® is substantially equivalent to the predicate device the MENTOR® MemoryShape™ Resterilizable Gel Breast Implant Sizer cleared under K151055. The proposed device Intraoperative, Single-use, Sterile, Silicone Breast Sizers Motiva Implant Matrix® is comparable to the predicate device with respect to product labeling, intended use, patient population, performance testing, technological characteristics, and safety characteristics. The predicate device is identified with the product Code MRD. It uses the common name: Sizer, Mammary, Breast Implant Volume and is unclassified.

DEVICE DESCRIPTION [807.92(A)(4)]

Intraoperative, Single-use, Sterile, Silicone Breast Sizers Motiva Implant Matrix® are sizing devices designed for temporary intraoperative placement, to assist in determining the desired breast implant volume and shape for each patient prior to implantation of a

Motiva Implant Matrix® silicone breast implant. They are used during breast augmentation or reconstruction procedures.

The Intraoperative, Single-use, Sterile, Silicone Breast Sizers Motiva Implant Matrix® are constructed with a low diffusion shell featuring a barrier layer between various layers of silicone elastomer to minimize gel diffusion; a patch, and cohesive restricted medical grade silicone gel, which is aimed for intraoperative temporary implantation only. The filling gel is tinted with pigments, in order for the Round Sizers to be clearly differentiated from the long term implantable devices.

The Intraoperative, Single-use, Sterile, Silicone Breast Sizers Motiva Implant Matrix® have been designed to match every Motiva Implant Matrix® silicone breast implant reference, and are therefore available in the same range of bases or diameters, projections and volumes as the long term implants.

INDICATIONS FOR USE [807.92(A)(5)]

Intraoperative, Single-use, Sterile, Silicone Breast Sizers Motiva Implant Matrix® are temporary intraoperative placement devices used during breast augmentation or reconstruction procedures to assist the surgeon in determining the appropriate size of the long-term breast implant to use.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES [807.92(a)(6)]

The proposed device, Intraoperative, Single-Use, Sterile, Silicone Breast Sizers Motiva Implant Matrix®, and the predicate device, MENTOR® MemoryShape™ Resterilizable Gel Breast Implant Sizer, have very similar safety and technological characteristics.

Both proposed and predicate devices are the same type of implant and share the same Indications for Use. Both implants are made with the same outer Silicone Elastomer shell material and filled with silicone gel, and biocompatible for limited, tissue/bone contact implant device.

Both the proposed and predicate devices are provided sterile, and packaged in sterile barrier packaging with a shelf life of five (5) years.

While the proposed device is intended for single use, the predicate device can be re-sterilized by the user for a total of 10 times. The proposed device has an option for including an RFID transponder for traceability, the predicate device does not have this option.

Substantial Equivalence

The indications for use for the predicate device is substantially equivalent to the proposed indications for use for the Intraoperative, Single-Use, Sterile, Silicone Breast Sizers Motiva Implant Matrix®. Any differences in the technological characteristics between the devices do not raise any new issues of safety or effectiveness. Thus, the Intraoperative, Single-Use, Sterile, Silicone Breast Sizers Motiva Implant Matrix® is substantially equivalent to the predicate device.

Performance Data [807.92(b)]

All necessary bench testing was conducted on the Intraoperative, Single-Use, Sterile, Silicone Breast Sizers Motiva Implant Matrix® to support a determination of substantial

equivalence to the predicate device.

Non-clinical Testing Summary [807.92(b)(1)]:

The non-clinical, bench testing included:

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

The collective results of the non-clinical testing demonstrate that the materials chosen, the manufacturing processes, and design of the Intraoperative, Single-Use, Sterile, Silicone Breast Sizers Motiva Implant Matrix® meet the established specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that the Intraoperative, Single-Use, Sterile, Silicone Breast Sizers Motiva Implant Matrix® does not raise new questions of safety or effectiveness for temporary insertion intraoperatively to determine (or evaluate) the size and shape of the Motiva Breast Implant when compared to the predicate device.

Clinical Testing Summary [807.92(b)(2)]:

This section is not applicable. No clinical testing was performed to support this 510(k) submission.

PREMARKET NOTIFICATION CONCLUSIONS [807.92(B)(3)]

The proposed device, Intraoperative, Single-Use, Sterile, Silicone Breast Sizers Motiva Implant Matrix® is substantially equivalent to the predicate device, MENTOR® MemoryShape® Resterilizable Gel Breast Implant Sizer. All non-clinical tests demonstrate that the Intraoperative, Single-Use, Sterile, Silicone Breast Sizers Motiva Implant Matrix® is as safe and as effective as the predicate device.

SUMMARY

The Intraoperative, Single-Use, Sterile, Silicone Breast Sizers Motiva Implant Matrix® is substantially equivalent to the predicate device.