October 13, 2023

Motiva USA LLC
Rosalyn d'Incelli
VP Clinical and Medical Affairs
125 East De la Guerra St, Suite 203A
Santa Barbara, California 93101

Re: K211676
Trade/Device Name: Motiva Flora SmoothSilk Tissue Expander
Regulatory Class: Unclassified
Product Code: LCJ
Dated: December 27, 2022
Received: December 28, 2022

Dear Rosalyn d'Incelli:

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/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 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 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,

David Krause -S

David Krause, Ph.D.
Deputy Director
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K211676

Device Name
Motiva Flora® SmoothSilk® Tissue Expander

Indications for Use *(Describe)*

Motiva Flora® SmoothSilk® Tissue Expanders are intended for temporary (less than six months) subcutaneous or submuscular implantation to develop surgical flaps and additional tissue coverage required in a wide variety of applications, particularly to aid in reconstruction following mastectomy, to aid in the treatment of underdeveloped breasts and to aid treatment of soft tissue deformities.

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.

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510(k) SUMMARY

Device Trade Name:	Motiva Flora® SmoothSilk® Tissue Expander K211676/S001
Device Common Name	Expander, Skin, Inflatable
Device Class:	Unclassified, Pre-Amendment
Panel	General & Plastic Surgery
Product Code:	LCJ
Predicate Device:	Sientra Silicone Tissue Expander (K070303)
Owner/Submitter:	Motiva USA LLC
Address/Number:	125 East De la Guerra St, Suite 203A, Santa Barbara, CA 93101 Tel: +1 (805) 452-5421
Regulatory Contact:	Rosalyn d'Incelli
Date Prepared:	July 25, 2023

DEVICE DESCRIPTION

The Motiva Flora® SmoothSilk® Tissue Expander (MFSTE) is intended for temporary subcutaneous or submuscular implantation to develop surgical flaps and additional tissue coverage and is not intended for use beyond six (6) months. All MFSTEs require periodic, incremental inflation with sterile saline for injection until the desired tissue expansion is developed. Once the desired tissue expansion is achieved, the tissue expander is surgically removed and a breast implant is inserted within the breast pocket.

The MFSTE is constructed of successive cross- linked layers of silicone elastomer with an Integrated Injection Port system for incremental expander filling. The Tissue Expanders are available in a range of sizes to meet diverse patient needs and achieve individualized aesthetic results. The MFSTE has a controlled surface architecture produced by the mandrel imprinting technique with an average roughness of 4 microns. Each MFSTE is supplied sterile.

The injection port is dome-shaped with a radiofrequency identification (RFID) coil embedded in the needle stop. This needle stop prevents inadvertent puncture through the base of the injection port during the filling process.

The injection port is found with the Motiva Flora® Port Locator accessory through the air wound coil's RFID signal placed inside the needle stop. The RFID wireless system comprises two components: the tag and the reader. The Motiva Flora® Port Locator (the reader) has antennas that emit radio waves and receive the signal coming from the RFID coil tag in the needle stop to locate the center of the injection port. The user interface of the Motiva Flora® Port Locator includes LED lights to guide the user during the process. This is an innovative technology not available in other tissue expanders on the market.

In addition, the RFID transponder functions as a traceability feature, which provides a unique electronic serial number (ESN) for each expander. The ESN allows access to a database with the device information (serial and lot number, size, projection, model, manufacturing date, etc.).

Additional design features of the MFSTE include a non-ferromagnetic component design that allows the device to be used with Magnetic Resonance (MR) and Computerized Tomography (CT) under certain conditions.

The MFSTE includes six (6) fixation tabs (TrueFixation®) to provide the surgeon options to suture the tissue expander in the breast pocket. Another design feature is its reinforced base.

INTENDED USE/INDICATIONS FOR USE

For temporary (less than six months) subcutaneous or submuscular implantation to develop surgical flaps and additional tissue coverage required in a wide variety of applications, particularly to aid in reconstruction following mastectomy, to aid in the treatment of underdeveloped breasts and to aid treatment of soft tissue deformities.

SUMMARY/COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The MFSTE and the Predicate Device have the same indications for use, design principles, and materials. As shown below, the MFSTE and Predicate Device have similar technological characteristics and ranges of volumes, sizes and projections.

Characteristic	Subject Device	Predicate Device
Average Shell Surface Roughness	≤ 10 microns	≤ 10 microns
Volume	260cc - 995cc	250cc - 900cc
Size, Width	11.0 cm - 16.0 cm	11.0 cm - 16.0 cm
Size, Height	9.0 cm - 16.5 cm	9.0 cm - 14.7 cm
Projection	6.7 cm - 8.8 cm	5.0 cm - 8.5 cm

Both devices' tissue expansion mode of action is based on incremental filling of a silicone shell with sterile saline fluid to stretch the surrounding tissue. The Subject and Predicate Device both use a port location device to identify the integral injection port.

Substantial equivalence was demonstrated primarily by physical and mechanical testing including comparative testing and evaluation of material properties, biological, chemical, and physical properties.

The following includes a list of the Technological Characteristics of the MFSTE and Predicate Device, which have been determined to be the same or substantially equivalent.

- Indications for Use
- Shell Surface
- Dimension Range.
- Mechanical Performance
- Injection Port
- Port Location Methodology
- Materials of Construction

The differences between the MFSTE and the Predicate Device are described below.

The MFSTE device uses a novel RFID tag and reader system for location of the injection port that is different from the magnetically detectable injection port location system used by the Predicate Device. Both products require a port location tool, but the MFSTE uses the Port Locator Accessory, which functions as an RFID reader, while the Predicate Device uses a Magnet Accessory.

Additionally, the MFSTE is labeled as "MR Conditional". Therefore, the patients may undergo MR imaging under specific MR conditions, while the Predicate Device is labeled "MR Unsafe".

The MFSTE includes six (6) fixation tabs (as compared to the two (2) fixation tabs for the Predicate Device) that are located on the perimeter of the tissue expander, providing the surgeon more options to secure the tissue expander within the breast pocket.

SUMMARY OF PERFORMANCE TESTING

Biocompatibility Testing:

Biocompatibility testing was conducted for both the MFSTE and Port Locator in accordance with ISO 10993-1:2018, *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process* and FDA's guidance document titled, Use of International Standard ISO 10993-1:2020, *"Biological Evaluation of medical devices – Part 1: Evaluation and Testing within a risk management process".* The results of the comprehensive biological safety evaluation based on the biocompatibility testing performed demonstrate that the MFSTE and Port Locator meet the requirements of ISO 10993-1:2018 and FDA's 2020 guidance.

Animal Testing:

GLP animal studies were conducted by NAMSA using the ovine model to compare the local tissue reaction of the MFSTE and the Sientra Silicone Tissue Expander (K070303). Histopathologic evaluation revealed that the tissue response to both the MFSTE and the Predicate

Device was a typical and expected response to a foreign body (ie., formation of a capsule around the implant) and was not considered adverse.

The MFSTE was considered to demonstrate equivalent biologic response as compared to the Predicate Device.

Mechanical Testing:

Mechanical testing was conducted in accordance with ASTM F1441-03:2014, *Standard Specification for Soft-Tissue Expander Devices*. The following mechanical testing was performed:

- Elongation
- Tensile Strength
- Break Force
- Joint Testing
- Overexpansion
- Needle Stop Penetration
- Injection Port Competence
- Critical and Non-Critical Fused or Adhered Joints

Sterilization Testing

Sterilization Validation was conducted in compliance with BS EN ISO 20857:2010, *Sterilization of health care products – Dry heat: Requirements for the development, validation, and routine control of a sterilization process for medical devices*. All testing met the requirements of the Motiva Flora® SmoothSilk Tissue Expander.

All mechanical performance testing results met their pre-determined acceptance criteria, thus demonstrating that the MFSTE is substantially equivalent to the Predicate Device.

Port Locator Electrical Safety (ES) and Electromagnetic Compatibility (EMC) Testing:

Testing was conducted to address the ES and EMC considerations for the Motiva Flora® Port Locator ("Port Locator") accessory, which reads the passive RFID tag within the MFSTE to accurately locate the implanted tissue expander injection port. All ES and EMC testing was conducted in accordance with the IEC 60601 series consensus standards, the AIM Standard 7351731, and the FCC 47 CFR Part 15 Subparts B and C. The following ES and EMC testing was conducted:

Electrical Safety

- ANSI/AAMI ES 60601-1:2005/(R)2012, *Third Edition, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance*

- IEC 60601-1:2005 + AMD1:2012, *Third Edition, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance*
- IEC 60601-1-6:2010 + AMD1:2013, *Third Edition, Medical Electrical equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability*

Electromagnetic Compatibility

- IEC 60601-1-2:2015, *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*
- FCC 47 CFR Part 15 Subpart B, Unintentional Radiators
- FCC 47 CFR Part 15 Subpart C, Intentional Radiators
- AIM Standard 7351731 - *Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers Version 2*

All Electrical Safety and Electromagnetic Compatibility testing results met the essential requirement specifications for the Motiva Flora® Port Locator, demonstrating the device will properly fulfill its intended function.

Port Locator Software Testing:

Software testing was conducted in accordance with the *General Principles of Software Validation, Final Guidance for Industry and FDA Staff* (2002), and the Software Requirement Specification for Motiva Flora® Port Locator.

All software testing results met their pre-determined acceptance criteria, thus demonstrating that the proposed device complies with the required specifications.

MR Conditional:

Non-clinical testing demonstrated that the MFSTE is MR Conditional in accordance with ASTM F2052-15*, "Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment.";* ASTM F2213-06, *"Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment"*; ASTM F2182-11a, *"Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging";* and ASTM F2119-07, *"Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants"*. The following testing was performed:

- Magnetically Induced Displacement Force
- Magnetically Induced Torque
- Heating by RF Fields
- Image Artifact
- Exposure tests at 1.5-Tesla/64-MHz and 3-T/128-MHz

All testing results met the pre-determined acceptance criteria, demonstrating that the device poses no known hazards in specified MR environments with specified conditions of use.

CONCLUSION

The MFSTE is substantially equivalent to the legally marketed Predicate Device, the Sientra Silicone Tissue Expander (K070303). The MFSTE has the same intended use/indications for use, operating principle, and similar technological characteristics as the Predicate Device. Performance evaluations and comparative physical/mechanical testing demonstrated that the MFSTE and the Predicate Device are substantially equivalent and that there are no new issues of safety and effectiveness.