August 29, 2018

Allergan
Melissa Pathmajeyan, Ph.D.
Senior Manager
2525 Dupont Drive
Irvine, California 92612

Re: K182054
Trade/Device Name: Natrelle® 133S Tissue Expander
Regulatory Class: Unclassified
Product Code: LCJ
Dated: July 30, 2018
Received: July 31, 2018

Dear Dr. Pathmajeyan:

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

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)*

K182054

Device Name
Natrelle 133S Tissue Expander

Indications for Use *(Describe)*

The Natrelle 133S Tissue Expander can be used for breast reconstruction following mastectomy, treatment of underdeveloped breasts, and treatment of soft tissue deformities. The expander is intended for temporary subcutaneous or submuscular implantation and is not intended for use beyond six months.

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

I. SUBMITTER

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Contact Person:
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Date Prepared: August 23, 2018

II. DEVICE INFORMATION

Name of Device: Natrelle® 133S Tissue Expander

Common Name: Expander, Skin, Inflatable

Classification Regulation: Unclassified, Pre-Amendment

Product Code: LCJ

III. PREDICATE DEVICE

Natrelle® 133 *Plus* Tissue Expander (K143354)

This predicate has not been subjected to a design-related recall or any type of recall.

IV. REFERENCE DEVICES

MENTOR Artoura Breast Tissue Expander with Smooth Surface (K161176)

Natrelle® 133 Tissue Expanders with Suture Tabs (K102806)

V. DEVICE DESCRIPTION

Natrelle® 133S *Plus* Tissue Expanders are designed to develop tissue flaps as part of two-stage reconstruction mammoplasty. The devices are constructed from silicone

elastomer and consist of a smooth surface expansion envelope, an orientation line, suture tabs, a MAGNA-SITE® integrated injection site, and a stable base to enable outward expansion. The tissue expanders are available in multiple styles and sizes to meet diverse surgical needs.

The MAGNA-SITE® injection site and MAGNA-FINDER® Xact external locating device contain rare-earth, permanent magnets for an accurate injection system. When the MAGNA-FINDER® Xact external locating device is passed over the surface of the tissue being expanded, its rare-earth, permanent magnet indicates the location of the MAGNA-SITE® injection site. The injection site is self-sealing and includes a titanium needle guard to prevent inadvertent puncture through the base of the injection site.

VI. INDICATIONS FOR USE

The Natrelle® 133S Tissue Expander can be used for breast reconstruction following mastectomy, treatment of underdeveloped breasts, and treatment of soft tissue deformities. The expander is intended for temporary subcutaneous or submuscular implantation and is not intended for use beyond six months.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE

The Natrelle® 133S Tissue Expander has the same fundamental technological characteristics as the predicate device. Like the predicate, the Natrelle® 133S Tissue Expander is composed of a silicone expansion envelope that expands with sequential injections of sterile saline. Both the predicate and the Natrelle® 133S Tissue Expander utilize an integrated, self-sealing magnetic injection site that can be located using a magnetic locating device. Compared to the BIOCELL® textured shell surface on the predicate device, the Natrelle® 133S Tissue Expander has a smooth surface shell. The Natrelle® 133S Tissue Expander also features a clear orientation line compared to a blue orientation line on the predicate; an increased number of suture tabs; and a modified insert disc composition with a reinforced ring comprised of the same materials as suture tabs on the reference device, Natrelle® 133 Tissue Expanders with Suture Tabs. None of these additional minor changes modify device functionality. All device dimensions, materials of construction, and other device features remain the same.

Performance Data:

Non-clinical performance data including mechanical testing data were submitted to support clearance of Natrelle® 133S Tissue Expanders. Testing was conducted according to methods prescribed by ASTM F1441-03 *Standard Specification for Soft-Tissue Expanders (2003)* and included physical properties of the shell, bond strength at non-critical and critical joints, and injection port competence. The testing was performed as required by the conducted risk analysis to verify and validate that the design outputs of the modified device met design input requirements. All pre-established acceptance criteria were met.

VIII. CONCLUSIONS

The Natrelle® 133S Tissue Expander has the same intended use, indications for use and fundamental scientific technology as the predicate device, the Natrelle® 133 *Plus* Tissue Expander. The results of the risk evaluations and non-clinical testing demonstrate that the design features of the Natrelle® 133S Tissue Expander do not raise different questions of safety and effectiveness or negatively impact safety and effectiveness (relative to the predicate device). Therefore, the Natrelle® 133S Tissue Expander is substantially equivalent to the Natrelle® 133 *Plus* Tissue Expander (predicate device) cleared under K143354.