December 21, 2018

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

Re: K180826
Trade/Device Name: Natrelle 133 Plus MICROCELL Tissue Expander
Regulatory Class: Unclassified
Product Code: LCJ
Dated: November 20, 2018
Received: November 23, 2018

Dear Melissa 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,

Cynthia Chang -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)*
K180826

Device Name
Natrelle® 133 Plus MICROCELL™ Tissue Expander

Indications for Use *(Describe)*
The Natrelle® 133 Plus MICROCELL™ Tissue Expander can be utilized for breast reconstruction after mastectomy, correction of an underdeveloped breast, scar revision, and tissue defect procedures. 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

Date Prepared:

December 14, 2018

510(k) Owner's Name and Contact Information:

Allergan
Contact Person: Melissa Pathmajeyan
2525 Dupont Drive
Irvine, CA 92612
Email: pathmajeyan_melissa@allergan.com
Phone: (714) 246-5919
Fax: (714) 796-9724

Device Information:

Proprietary Name: Natrelle® 133 *Plus* MICROCELL™ Tissue Expander
Common Name: Expander, Skin, Inflatable
Classification Regulation: Unclassified, Pre-Amendment
Product Code: LCJ

Predicate Device:

Natrelle® 133 *Plus* Tissue Expander (K143354)

Device Description:

Natrelle® 133 *Plus* MICROCELL™ Tissue Expanders are designed to develop tissue flaps as part of 2-stage reconstruction mammoplasty. The devices are constructed from silicone elastomer and consist of an expansion envelope with a MICROCELL™ textured surface, an orientation line, three 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 expander, 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.

Intended Use/Indications for Use:

The Natrelle® 133 *Plus* MICROCELL™ Tissue Expander can be utilized for breast reconstruction after mastectomy, correction of an underdeveloped breast, scar revision and tissue defect procedures. The expander is intended for temporary subcutaneous or submuscular implantation and is not intended for use beyond six months.

Technological Characteristics:

The Natrelle® 133 *Plus* MICROCELL™ Tissue Expander has the same fundamental technological characteristics as the predicate device. Like the predicate, the Natrelle® 133 *Plus* MICROCELL™ Tissue Expander is composed of a silicone expansion envelope with a textured surface, which expands with sequential injections of sterile saline. Both the predicate and the Natrelle® 133 *Plus* MICROCELL™ 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 on the predicate device, the Natrelle® 133 *Plus* MICROCELL™ Tissue Expander has a MICROCELL textured shell. Allergan's MICROCELL surface texture has a lower surface area than Allergan's BIOCELL surface texture. All materials of construction, dimensions, and other device features remain the same.

Performance Data:

Non-clinical performance data, including mechanical testing data and biocompatibility data, were submitted to support clearance of Natrelle® 133 *Plus* MICROCELL™ Tissue Expanders. Where appropriate, testing was conducted according to methods prescribed by relevant ASTM and/or ISO standards. All pre-established acceptance criteria were met.

Conclusions:

The Natrelle® 133 *Plus* MICROCELL™ 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 non-clinical testing demonstrate that the design features of the Natrelle® 133 *Plus* MICROCELL™ 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® 133 *Plus* MICROCELL™ Tissue

Expander is substantially equivalent to the Natrelle® 133 *Plus* Tissue Expander (predicate device) cleared under K143354.