DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 20, 2015

Allergan Incorporated
Mr. Bruce Krattenmaker
Vice President, Regulatory Affairs
2525 Dupont Drive
Irvine, California 92612

Re: K143354
Trade/Device Name: Natrelle® 133 Plus Tissue Expander
Regulatory Class: Unclassified
Product Code: LCJ
Dated: July 16, 2015
Received: July 20, 2015

Dear Mr. Krattenmaker:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143354

Device Name
Natrelle® 133 Plus Tissue Expander

Indications for Use *(Describe)*
The Natrelle® 133 Plus Tissue Expanders 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) SUMMARY

Date Prepared:

November 20, 2014

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

Allergan
Contact Person: Bruce Krattenmaker
2525 Dupont Drive
Irvine, CA 92612
Phone: (714) 246-6182
Fax: (714) 796-9724

Device Information:

Proprietary Name:	Natrelle® 133 Plus Tissue Expander
Common Name:	Tissue Expander
Classification Name:	Expander, Skin, Inflatable
Product Code:	LCJ

Predicate Device:

Mentor CPX 4 Breast Tissue Expanders and Mentor CPX 4 with Suture Tabs Breast Tissue Expanders (K130813)

Device Description:

The Natrelle® 133 Plus 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 BIOCELL® textured surface, an orientation line, three suture tabs (optional), 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.

Intended Use/Indications for Use:

The Natrelle® 133 Plus Tissue Expanders 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 Tissue Expander has the same fundamental technological characteristics as the predicate device. Like the predicate, the Natrelle® 133 Plus 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 Tissue Expander utilize an integrated, self-sealing magnetic injection site that can be located using a magnetic locating device.

Performance Data:

Non-clinical performance data were submitted to support the substantial equivalence of the Natrelle® 133 Plus Tissue Expander to the predicate device. These data included biocompatibility data and mechanical testing data. 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 Tissue Expander has the same intended use and indications for use as the predicate device. The results of non-clinical testing demonstrate that the design features of the Natrelle® 133 Plus 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 Tissue Expander is substantially equivalent to the tissue expanders marketed by Mentor (K130813).