January 16, 2026

AbbVie
Melissa Pathmajeyan
Director, Global Regulatory Affairs
2525 Dupont Dr.
Irvine, California 92612

Re: K254126
Trade/Device Name: Natrelle 133S Tissue Expanders
Regulatory Class: Unclassified
Product Code: LCJ
Dated: December 19, 2025
Received: December 19, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Alicia Hemphill -S

Digitally signed by Alicia Hemphill -S
Date: 2026.01.16 14:11:45 -06'00'

Alicia Hemphill, M.S.
Assistant Director
DHT4B: Division of Plastic and
Reconstructive Surgery Devices
OHT4: 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K254126

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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY (K254126)

Submitter's Name and Contact Information:

AbbVie
Contact Person: Melissa Pathmajeyan, Ph.D.
2525 Dupont Drive
Irvine, CA 92612
Email: melissa.pathmajeyan@abbvie.com
Phone: (714) 246-5919
Date Prepared: December 19, 2025

Device Information:

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

Predicate Device:

Natrelle® 133S Tissue Expander (K182054)

Device Description:

Natrelle® 133S 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.

Intended Use/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.

Technological Characteristics:

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 smooth surface 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 predicate, a 21-Gauge needle infusion set accessory is not provided in the packaging configuration. All device dimensions, materials of construction, and device features remain the same.

Performance Data:

Per the risk analysis and design control procedures, additional performance data was not required.

Conclusions:

The Natrelle® 133S Tissue Expander has the same intended use, indications for use and fundamental scientific technology as the predicate device. The results of the risk evaluations 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 device originally cleared under K182054.