June 2, 2021

Allergan Aesthetics
Kelly Carty
Executive Director, Regulatory Affairs
2525 Dupont Dr.
Irvine, California 92612

Re: K203229
Trade/Device Name: NATRELLE INSPIRA Single Use Sizers for Gel Implants
Regulatory Class: Unclassified
Product Code: MRD
Dated: April 30, 2021
Received: May 3, 2021

Dear Kelly Carty:

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,

Cindy Chowdhury, Ph.D., M.B.A.
Assistant Director
DHT4B: Division of Infection Control
and Plastic 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)*
K203229

Device Name
NATRELLE INSPIRA® Single Use Sizers

Indications for Use *(Describe)*
NATRELLE INSPIRA® Single Use Sizers are used during breast augmentation or reconstruction procedures to assist the surgeon in determining the appropriate size breast implant.

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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5. 510(K) SUMMARY

Date Prepared:

April 27, 2020

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

Allergan
Contact Person: Kelly Carty
2525 Dupont Drive
Irvine, CA 92612
Email: Carty_Kelly@allergan.com
Phone: (714) 246-6180

Device Information:

Proprietary Name: NATRELLE INSPIRA® Single Use Sizers

Common Name: Sizer, Mammary, Breast Implant Volume

Classification Regulation: Unclassified, Pre-Amendment

Product Code: MRD

Predicate Device:

Natrelle® Re-Sterilizable Breast Implant Sizers (K831566)

Reference Device:

Natrelle® 133S Tissue Expander (K182054)

Device Description:

NATRELLE INSPIRA® Single Use Sizers are designed for temporary intraoperative placement, to assist in determining the desired breast implant volume. They are used during breast augmentation or reconstruction procedures.

NATRELLE INSPIRA® Single Use Sizers are constructed of a smooth silicone elastomer

shell and are filled with responsive gel that contains the colorant cobalt aluminate blue spinel at a concentration of 0.1%. They have been designed to match the dimensions of the NATRELLE INSPIRA® breast implants.

NATRELLE INSPIRA® Single Use Sizers are supplied sterile and are for single patient use, one sizer per breast.

Intended Use/Indications for Use:

NATRELLE INSPIRA® Single Use Sizers are used during breast augmentation or reconstruction procedures to assist the surgeon in determining the appropriate size breast implant.

Technological Characteristics:

NATRELLE INSPIRA® Single Use Sizers have the same fundamental technological characteristics as the predicate device. Like the predicate, the NATRELLE INSPIRA® Single Use Sizers are constructed of a smooth silicone elastomer shell and are filled with responsive gel.

These devices will maintain all functionalities and performance from the current RSS (Resterilizable sizers) product line with the following differences:

- A new silicone gel will be used. The new gel to be used in the Single Use Sizers differs from the gel in the predicate in the following aspects:
  - New supplier
  - Sizer gel is qualified for short-term implant whereas the gel in the predicate is qualified for long-term implant.
  - Colorant (cobalt aluminate blue spinel at a concentration of 0.1%) added
- The stamp on the shell is updated to reflect the new sizer name
- The labeling has been updated to reflect the product name as well as to remove instructions related to cleaning and resterilization

Performance Data:

Non-clinical performance data including mechanical testing and biocompatibility data were submitted to support clearance of NATRELLE INSPIRA® Single Use Sizers. Where appropriate, testing was conducted according to methods prescribed by relevant standards. 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.

Conclusions:

The NATRELLE INSPIRA® Single Use Sizers have the same intended use, indications for use and fundamental scientific technology as the predicate device, Natrelle® Re-Sterilizable Breast Implant Sizers (K831566). The results of the risk evaluations and non-clinical testing demonstrate that the design features of the NATRELLE INSPIRA® Single Use Sizers do not raise different questions of safety and effectiveness or negatively affect safety and effectiveness (relative to the predicate device). Therefore, the NATRELLE INSPIRA® Single Use Sizers are substantially equivalent to the Natrelle® Re-Sterilizable Breast Implant Sizers (predicate device) cleared under K831566.