November 16, 2020

Sientra, Inc
Joann Kuhne
Vice President of Regulatory Affairs, Quality Assurance and Clinical
420 South Fairview Avenue, Suite 200
Santa Barbara, California 93117

Re: K200706
Trade/Device Name: Sientra OPUS Silicone Gel Breast Implant Sizer
Regulatory Class: Unclassified
Product Code: MRD
Dated: October 22, 2020
Received: October 23, 2020

Dear Joann Kuhne:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200706

Device Name
Sientra OPUS® Silicone Gel Breast Implant Sizer

Indications for Use *(Describe)*
The Sientra OPUS® Silicone Gel Breast Implant Sizer is a single-use, sterile, intraoperative device indicated for temporary placement during breast augmentation or reconstruction procedures to assist the surgeon in determining the appropriate size of the long-term Sientra OPUS® Breast Implant to be implanted.

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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5.0 510(k) Summary [807.92(a)(1)]

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Date Prepared: March 16, 2020

Device Information [807.92(a)(2)]

Proprietary Name:	Sientra OPUS® Silicone Gel Breast Implant Sizer
Classification Name:	Sizer, Mammary, Breast Implant
Classification:	Unclassified
Review Panel:	General and Plastic Surgery Devices Panel
Product Code:	MRD
Predicate Device:	Intraoperative, Single-Use, Sterile, Silicone Breast Sizers Motiva Implant Matrix® (K183163)

Predicate Device [807.92(a)(3)]

The *Sientra OPUS® Silicone Gel Breast Implant Sizer* ("Sientra Gel Sizer") is substantially equivalent to the *Intraoperative, Single-Use, Sterile, Silicone Breast Sizer Motiva Implant Matrix®*, cleared under K183163. The *Sientra OPUS® Silicone Gel Breast Implant Sizer* is comparable to the predicate device with respect to intended use, technological characteristics, performance testing, safety characteristics, and product labeling. The predicate device holds the same device classification name of *Sizer, Mammary, Breast Implant, Volume,* and the regulation is unclassified.

Device Description [807.92(a)(4)]

The *Sientra OPUS® Silicone Gel Breast Implant Sizer* is a single-use, sterile, intraoperative device indicated for temporary placement during breast augmentation or reconstruction procedures to assist the surgeon in determining the appropriate size Sientra Breast Implant to be implanted. The Sientra Gel Sizers are designed to complement the portfolio of *Sientra OPUS® Silicone Gel Breast Implants* ("Breast Implants" or "Implants"), and are therefore available in the same range of styles, dimensions and fill volume as Sientra Implants.

The *Sientra OPUS® Silicone Gel Breast Implant Sizers* are constructed with a smooth-surfaced, silicone elastomer shell and a filler made of clear, high-strength silicone gel. Sientra's Gel Sizers have been demonstrated to be biocompatible. The printing on the exterior of the Gel Sizer shell is clearly marked, "*SIZER*", "*SINGLE USE ONLY*", and "*DO NOT IMPLANT*", to clearly differentiate the Gel Sizers from Sientra's OPUS Breast Implants. Each Sientra Gel Sizer is dry-heat-sterilized, for single patient use only, and is not intended for long-term implantation or re-sterilization.

Indications for Use [807.92(a)(5)]

The *Sientra OPUS® Silicone Gel Breast Implant Sizer* is a single-use, sterile, intraoperative device indicated for temporary placement during breast augmentation or reconstruction procedures to assist the surgeon in determining the appropriate size of the long-term Sientra OPUS® Breast Implant to be implanted.

Comparison of the Technological Characteristics with the Predicate Device [807.92(a)(6)]

The proposed device, *Sientra OPUS® Silicone Gel Breast Implant Sizer*, and the predicate device, *Intraoperative, Single-Use, Sterile, Silicone Breast Sizers Motiva Implant Matrix®*, are both single-use silicone gel sizers and share the same Indications for Use. In addition, they are both constructed of an outer silicone elastomer shell material, filled with silicone gel and are biocompatible. They are each provided sterile and are packaged in sterile barrier packaging with a shelf-life of five years. Furthermore, both the proposed and predicate devices were subjected to similar performance testing.

Performance Data [807.92(b)]

All necessary bench testing was conducted to support a determination of substantial equivalence of the *Sientra OPUS® Silicone Gel Breast Implant Sizer* to the predicate device.

Non-clinical Testing Summary [807.92(b)(1)]

The following performance testing was conducted on Sientra's Gel Sizer:

- Gel Cohesion
- Elongation
- Break Force
- Tensile Set
- Patch to Shell Joint Integrity
- Implant Marking Verification and Rub Testing

Results of the performance testing demonstrate that the *Sientra OPUS® Silicone Gel Breast Implant Sizer* met the predetermined acceptance criteria and thus is substantially equivalent to the predicate device. In addition, the collective non-clinical testing demonstrates that the Sientra OPUS® Silicone Gel Breast Implant Sizer does not raise

new questions of safety or effectiveness for its intended use when compared to the predicate device.

Clinical Testing Summary [807.92(b)(2)]

This section is not applicable. No clinical testing was performed to support this 510(k) submission.

Premarket Notification Conclusions [807.92(b)(3)]

The proposed and predicate devices are similar in terms of intended use, technological characteristics, safety characteristics, and performance testing. Any differences in the technological characteristics between the proposed and predicate devices to not raise any new issues of safety or effectiveness. Thus, the proposed *Sientra OPUS® Silicone Gel Breast Implant Sizer* is substantially equivalent to the predicate device.