October 27, 2021

Sientra, Inc
Denise Dajles
Vice President, R&D and Regulatory
420 South Fairview Ave, Suite 200
Santa Barbara, California 93117

Re: P070004/S033
Trade/Device Name: Sientra OPUS Silicone Gel Breast Implants
Product Code: FTR
Filed: August 9, 2021

Dear Denise Dajles:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) supplement, which requested approval for changes to the patient and physician labeling including a boxed warning and a patient decision checklist. Based upon the information submitted, the PMA supplement is approved. You may begin commercial distribution of the device as modified by your PMA supplement in accordance with the conditions described below.

The sale and distribution of this device is restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the Act). As a restricted device, your device is subject to the requirements in section 502(q) and (r) of the Act, in addition to other FDA requirements governing the manufacture, distribution, and marketing of devices. FDA has determined that the restrictions under section 515(d)(1)(B)(ii) are necessary to provide reasonable assurance of the safety and effectiveness of the device.

The sale and distribution of Sientra OPUS Silicone Gel Breast Implants is restricted to users and/or user facilities that provide information to patients about the risks and benefits of this device prior to its use in the form and manner specified in approved labeling to be provided by Sientra, Inc. The sale and distribution of Sientra OPUS Silicone Gel Breast Implants is restricted to users and/or user facilities that convey such information to patients in the following manner:

1. The patient brochure “Patient Decision Checklist”, which is part of the approved labeling and will serve as a collective source of information for the patient, is provided to the prospective patient by the implanting physician.

2. The patient brochure “Patient Decision Checklist” is reviewed by the implanting physician with the patient to assure that the patient understands the risks, benefits, and other information associated with implantation of Sientra OPUS Silicone Gel Breast Implants.

3. The patient is provided an opportunity to initial and sign the designated portions of the patient brochure "Patient Decision Checklist" to document that the patient has been informed of the risks, benefits, and other information associated with implantation of Sientra OPUS Silicone Gel Breast Implants and has determined to proceed with the implantation of Sientra OPUS Silicone Gel Breast Implants.

4. The designated portion of the patient brochure "Patient Decision Checklist" is signed by the implanting physician to document that the physician has discussed the risks and benefits of Sientra OPUS Silicone Gel Breast Implants as well as the risks and benefits of available alternatives and has addressed all questions from the patient.

FDA is also requiring that the following be included in device labeling and any advertising for Sientra OPUS Silicone Gel Breast Implants: "The sale and distribution of this device is restricted to users and/or user facilities that provide information to patients about the risks and benefits of this device in the form and manner specified in the approved labeling provided by Sientra, Inc." The device labeling approved in this PMA supplement meets these requirements.

Continued approval of the PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. This report, identified as "Annual Report" and bearing the applicable PMA reference number, should be submitted to the address below and must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events. The Annual Report should indicate the beginning and ending date of the period covered by the report and must include the information required by 21 CFR 814.84(b) and any other information required through the device's PMA approval order per 21 CFR 814.84(a).

This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final Unique Device Identification (UDI) rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR 830 Subpart E). Additionally, 21 CFR 814.84(b)(4) requires PMA annual reports submitted after September 24, 2014, to identify each device identifier currently in use for the subject device, and the device identifiers for devices that have been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013. Combination Products may also be subject to UDI requirements (see 21 CFR 801.30). For more information on these requirements, please see the UDI website, https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-udi-system.

Before making any change affecting the safety or effectiveness of the PMA device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39. All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. For more information, please refer to the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process"

https://www.fda.gov/media/81431/download.

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52 for devices or post-marketing safety reporting (21 CFR 4, Subpart B) for combination products, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems and on combination product post-marketing safety reporting is available at https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products).

In accordance with the recall requirements specified in 21 CFR 806.10 for devices or the post-marketing safety reporting requirements (21 CFR 4, Subpart B) for combination products, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the Act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls.

CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with a copy of all final labeling. Final labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the final labeling is identical to the labeling approved in draft form. If the final labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment. Please also make the updated labeling publicly available on your website 30 days from the date of this letter. In addition, please contact and inform all customers of the updated labeling changes within 30 days of this approval.

All required documents should be submitted, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning this approval order, please contact Tajanay R Ki at 301-796-6441 or Tajanay.Ki@fda.hhs.gov.

Sincerely,

Cynthia Chang -S

Cynthia J. Chang, Ph.D.
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