September 26, 2024

Motiva USA, LLC
Rosalyn D'incelli
Vice President, Clinical and Medical Affairs
2543 Mesa School Lane
Santa Barbara, California 93109

Re: P230005
Trade/Device Name: Motiva SmoothSilk Round Ergonomix Silicone Gel-Filled Breast Implants, Motiva SmoothSilk Round Silicone Gel-Filled Breast Implants
Product Code: FTR
Filed: February 24, 2023
Amended: February 13, 2024, July 2, 2024

Dear Rosalyn D'incelli:

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) for the Motiva SmoothSilk Round Ergonomix Silicone Gel-Filled Breast Implants, Motiva SmoothSilk Round Silicone Gel-Filled Breast Implants. This device is indicated for:

- The Motiva SmoothSilk Round and SmoothSilk Round Ergonomix breast implants are indicated for breast augmentation for women of at least 22 years old. Breast augmentation includes primary breast augmentation to increase the breast size, as well as revision surgery to correct or improve the result of an original primary breast augmentation surgery (i.e., revision-augmentation).

Based upon the information submitted, the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below. Although this letter refers to your product as a device, please be aware that some approved products may instead be combination products. The Premarket Approval Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm identifies combination product submissions.

The sale and distribution of this device are 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). The device is further restricted under section 515(d)(1)(B)(ii) of the act insofar as the labeling must specify the specific training or experience practitioners need in order to use the device and insofar as the sale and distribution of the device are restricted as specified below. The FDA has determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to all other applicable requirements, including those governing the manufacture, distribution, and marketing of devices.

The sale and distribution of Motiva SmoothSilk Round Ergonomix and Round Silicone Gel-Filled 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 Motiva USA, LLC. The sale and distribution of Motiva SmoothSilk Round Ergonomix and Round Silicone Gel-Filled 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 Motiva SmoothSilk Round Ergonomix and Round Silicone Gel-Filled 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 Motiva SmoothSilk Round Ergonomix and Round Silicone Gel-Filled Breast Implants and has determined to proceed with the implantation of Motiva SmoothSilk Round Ergonomix and Round Silicone Gel-Filled 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 Motiva SmoothSilk Round Ergonomix and Round Silicone Gel-Filled 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 Motiva SmoothSilk Round Ergonomix and Round Silicone Gel-Filled 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 Motiva USA, LLC.” The device labeling approved in this PMA supplement meets these requirements.

Expiration dating for this device has been established and approved at 5 years.

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. 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.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the PMA device, under 21 CFR 814.82(a)(9), the Annual Report 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, as FDA evaluates the continued safety and effectiveness of the device.

You must obtain approval of your post-approval study (PAS) protocol(s) within 60 days from the date of this order. Within 30 days of your receipt of this letter, you must submit a PMA supplement that includes a complete protocol of your post-approval study described below. Your PMA supplement should be clearly labeled as a "PMA Post-Approval Study Protocol" as noted below and submitted to the address below. Please reference the PMA number above to facilitate processing. If there are multiple protocols being finalized after PMA approval, please submit each protocol as a separate PMA supplement.

In addition to the Annual Report requirements, you must participate as a stakeholder in the National Breast Implants Registry. Furthermore, you must provide the following data in post-approval study (PAS) reports for each PAS listed below.

1. The Continuation of the Motiva Implants® Core Clinical Study (Post-Approval PMA Cohorts Study – PACS)

   Per agreement reached on September 25, 2024, the Post-Approval PMA Cohort Study protocol will consist of the continued follow-up of premarket cohorts. The study participants will be followed annually for 10 years in order to assess the long-term clinical performance of their device. The PACS data will be collected via annual physician follow-up evaluations. The study was designed as a 10-year open-label, prospective, multicenter clinical study. The study will include a total of 560 primary and revision augmentation subjects implanted with 1,119 Motiva Silicone Gel Implants with at least 3-years of follow-up. Follow-up will continue for 10 years with all patients who have RFID in their MOTIVA breast implants to be included in the MRI cohort along with those who were already enrolled in the MRI cohort. There were 23 implanting investigational sites: 20 study sites located in the United States and 3 study sites OUS, one located in Germany and two located in Sweden. All safety and effectiveness data will continue to be collected for all cohorts on adverse events, reoperations, patient satisfaction, physician satisfaction and quality of life through 10 years.

   Motiva must also update their patient and physician labeling to reflect 5 and 10 year PACS study findings on the safety and effectiveness of the devices, as soon as these data are available, as well as any other time point deemed necessary by FDA if significantly new information from this study becomes available.

   In addition, you must submit separate periodic reports on the progress of the PACS as follows:
   - On an annual basis, Motiva must submit a PACS progress report to FDA that includes: (1) the follow-up status of study subjects; and (2) a summary of findings for all study endpoints.
   - Motiva is also required to conduct Device Explant Analyses for all devices retrieved from women enrolled in the PACS. Motiva must report results of these explant analyses in the PACS progress reports.
   - The Final PACS Report will be submitted three (3) months from study completion (i.e., last subject’s last follow-up date).

2. Motiva Implants® New Enrollment Post-Approval Study

PAS Study Design:

Per agreement reached on September 25, 2024, a post-approval study will be performed. This is a new enrollment multicenter non-randomized prospective study including baseline (preoperative), operative and post operative data collection with patient surveys at baseline and years 1-10. Endpoints will include:

Purpose:

Assess selected safety and effectiveness issues not addressed during premarket studies.

Endpoints:

- Assess the patient reported incidence of Connective Tissue Disease (CTD) signs and symptoms using a fit-for-purpose instrument(s) and compare them among study groups (i.e., implanted vs controls).
- Measure the incidence of reproductive complications, cancer (including breast cancer), local complications (including suspected rupture), reoperation, and implant removal, and compare them among study groups (e.g., (a) Round compared to Round Ergonomix devices, (b) Non-White participants as compared to White participants (c) RFID devices compared to non-RFID devices and (d) implanted vs controls where data collection allows)
- Assess impact on imaging (MRI scans or ultrasound) between participants with RFID as compared to those without RFID

Enrollment Study Population and Sample Size Calculations:

This study will enroll:

- 1500 Primary Augmentation subjects implanted with the approved Motiva devices.
- 500 Revision Augmentation subjects implanted with the approved Motiva devices.
- 400 control subjects consisting of women who will undergo an aesthetic procedure other than breast implants.
- Sufficient sample size to assess a difference in CTD Signs/Symptoms between the Motiva implanted group and the control group
- Sufficient sample size to assess as will be agreed upon in the final protocol:
    - Round compared to Round Ergonomix devices
    - Non-White participants as compared to White participants and,
    - RFID devices compared to non-RFID devices

PAS Assessment Schedule:

- Assessments at Baseline and Years 1-10 and more frequent assessments as necessary

Data Analysis and Reporting:

Motiva must update their patient and physician labeling to reflect 5 and 10-year PAS study findings, as soon as these data are available, as well as any other timepoint deemed necessary by FDA if significantly new information from this study becomes available.

From the date of study protocol approval, you must meet the following timelines for the New Enrollment Post-Approval Study:

- First subject enrolled within 6 months
- 20% of subjects enrolled within 12 months
- 50% of subjects enrolled within 18 months
- 100% of subjects enrolled within 24 months

You must meet pre-defined targets for follow-up rates as specified in the PAS protocol.

Periodic reports including enrollment rates versus stated goals and follow-up rates versus stated goals on the progress of the PAS will be as follows:

- Endpoints and Data analysis per approved protocol.
- PAS Progress Reports will be submitted every six (6) months until subject enrollment has been completed, and annually thereafter, from the date of the PMA approval letter, unless otherwise specified by FDA. A data release plan will be submitted in the full protocol.
- If any enrollment milestones are not met, quarterly enrollment status reports will be submitted in addition to the periodic (6-month) PAS Progress Reports.
- The Final PAS Report will be submitted three (3) months from study completion (i.e., last subject's last follow-up date).
- In addition, analysis for all explanted devices retrieved will continue for all explanted devices retrieved during course of follow-up. Motiva is also required to conduct Device Explant Analyses for all devices retrieved from women enrolled in the PAS. Motiva must report results of these explant analyses in the PAS progress reports.

3. Device Explant Analysis

In addition to the studies listed above, MOTIVA must conduct non-PAS Device Explant Analyses for all MOTIVA Breast Implants that are retrieved in the commercial setting outside the post-approval studies, as per explant analysis protocol to be submitted along with the PAS Protocol. On an annual basis, MOTIVA must report the results of these Device Explant Analyses in the PMA Annual Reports.

Each PAS report should be submitted to the address below identified as a "PMA Post-Approval Study Report" in accordance with how the study is identified above and bearing the applicable PMA reference number.

Be advised that failure to comply with any post-approval requirement, including failure to initiate the study in a timely manner, meet enrollment milestones, meet follow-up compliance targets, or submit the required reports, constitutes grounds for FDA withdrawal of approval of the PMA in accordance with 21 CFR 814.82(c) and 814.46(a)(2).

Be advised that the failure to conduct any such study in compliance with the good clinical laboratory practices in 21 CFR part 58 (if a non-clinical study subject to part 58) or the institutional review board regulations in 21 CFR part 56 and the informed consent regulations in 21 CFR part 50 (if a clinical study involving human subjects) may be grounds for FDA withdrawal of approval of the PMA in accordance with 21 CFR 814.46(a)(3)-(4).

Be advised that protocol information, interim and final results will be published on the Post-Approval Studies Program Database Webpage, available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma_pas.cfm.

In addition, the results from any post approval study should be included in the labeling as these data become available. Under 21 CFR 814.39, any updated labeling must be submitted to FDA in the form of a PMA Supplement. For more information on post-approval studies, see the FDA guidance document entitled, "Procedures for Handling Post-Approval Studies Imposed by Premarket Approval Application Order" (https://www.fda.gov/media/71327/download).

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 Part 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 available at 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. Additional information about changes that may require a PMA supplement are provided in 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.

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 and process controls (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 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 Part 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. CDRH will notify the public of its decision to approve your PMA by making available, among other information, a summary of the safety and effectiveness data upon which the approval is based. The information can be found at https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/pma-approvals. Written requests for this information can also be made to the Food and Drug Administration, Dockets Management Branch, (HFA-305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by submitting a petition for review under section 515(g) of the act and requesting either a hearing or review by an independent advisory committee. FDA may, for good cause, extend this 30-day filing period.

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.

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 Alexander Nguyen, Ph.D. at Alexander.Nguyen@fda.hhs.gov.

Sincerely,

Cynthia Chang -S

Cynthia J. Chang, Ph.D.
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