U.S. FOOD & DRUG ADMINISTRATION

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.