DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Mentor Worldwide LLC
% Mr. Brian Kanerviko
Senior Director Regulatory Affairs
201 Mentor Drive
Santa Barbara, California 93111

JUN 14 2013

Re: P060028
MemoryShape™ Breast Implants (Style MM or Style 321)
Filed: October 6, 2006
Amended: November 3, 2006; February 7 and 8, 2008; February 9, 2009; May 18, June 22, and December 23, 2010; October 4, and November 30, 2011; April 12, and December 20, 2012; and February 25, 2013.
Procode: FTR

Dear Mr. Kanerviko:

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 MemoryShape™ Breast Implants. This device is indicated for females for the following uses (procedures):

- Breast augmentation for women 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 a primary breast augmentation surgery.

- Breast Reconstruction. Breast reconstruction includes primary reconstruction to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality. Breast reconstruction also includes revision surgery to correct or improve the results of a primary breast reconstruction surgery.

We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below.

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. 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 the many other FDA requirements governing the manufacture, distribution, and marketing of devices. More specifically, completion of your physician training program is required as a condition of access to your product. FDA will, however, allow a 90-day transition period for all current Core and Continued Access Study investigators, after which these physicians must also have completed the training program in order to have access to the Mentor product.

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

Continued approval of this 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. Two copies of 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 should 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 device, 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.

In addition to the conditions outlined above, you must conduct the following post-approval studies that will evaluate the long-term safety and effectiveness of your approved device.

1. Post-Approval PMA Cohort Study (PACS)

Per Post-Approval PMA Cohort Study protocol version dated January 22, 2010, this study will consist of the continued follow-up of premarket cohorts. Study participants will be followed annually for 10 years in order to assess the long-term clinical performance of their device. The Post-Approval PMA Cohorts Study (PACS) will include a total of 955 subjects. The PACS data are to be collected via annual physician follow-up evaluations and all patients in the study will have MRI at years 8 and 10. All safety and effectiveness endpoints evaluated at premarket will continue to be studied long-term. The safety endpoints include local complications, implant rupture, rheumatologic diseases and rheumatologic signs and symptoms. Descriptive statistics will be provided for all endpoints. The association between the studied endpoints and Mentor's approved device will be assessed as per protocol version dated January 22, 2010. Additional analyses will be performed as per agreement reached on September 11, 2012 (e-mail). Mentor is also required to conduct Device Explant Analyses for all devices retrieved from women enrolled in the PACS as outlined in the protocol version dated August 12, 2012. Mentor must report results of these explant analyses in the post-approval study Annual Report.

Mentor must also update their patient and physician labeling to reflect 10-year PACS study findings on the safety and effectiveness of the device, 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. On an annual basis, Mentor 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.

2. Post-approval Continued Access Study (PACAS)

Per Post-approval Continued Access Study protocol version dated April 18, 2013 (e-mail), the Post-Approval Continued Access Study (PACAS) will consist of the continued follow-up, for 5-years post-implantation, of approximately 350 subjects who were previously enrolled before the date of approval in the Continued Access Study and implanted with MemoryShape Medium Height Moderate Profile (CPG Style 321) Breast Implants. All safety endpoints evaluated premarket will continue to be studied through 5-years of follow-up. Descriptive statistics will be provided. Mentor is also required to conduct Device Explant Analyses for all devices retrieved from women enrolled in the PACAS as outlined in the protocol version dated August 12, 2012. Mentor must report results of these explant analyses in the post-approval study Annual Report.

On an annual basis and until the completion of 5year follow-up for all PACAS subjects, Mentor must submit a PAS progress report to the FDA that includes: patient compliance, a summary of findings for all study endpoints, and results of the device explant analyses for devices explanted within this study.

3. MemoryShape Post-Approval Study (MemoryShape PAS)

Per MemoryShape Post-approval Study protocol version October 25, 2012 (e-mail), this study is a newly enrolled cohort study in the US. The purpose of this study is to evaluate the long-term clinical performance of MemoryShape Breast Implants under general conditions of use in the postmarket environment. The study will enroll 2,518 women receiving MemoryShape Breast Implants and 300 women undergoing other aesthetic surgery as the comparison group. Study subjects will be followed annually for 10 years. Data will be collected on the following safety endpoints: connective tissue diseases (CTDs), rheumatologic and neurologic signs and symptoms, cancer (lung and breast, including the potential of breast implant interference with mammography and delay of breast cancer detection), suicide/attempted suicide, local complications (including infection, rupture; including rupture rate following mammography), reoperation and implant removal, reproductive complications in women who attempt to have children, lactation complications, and congenital deformities. The effectiveness will be assessed by participants' responses to questions addressing their perceived quality of life and satisfaction with their breast implants.

Data are to be collected via annual patient questionnaires. There will also be physician evaluations at years 1, 5, and 10. Descriptive statistics will be provided for the studied endpoints. In addition, the association between the studied endpoints and Mentor's approved device will be assessed as per protocol version dated October 25, 2012. Mentor is also required to conduct Device Explant

Analyses for all devices retrieved from women enrolled in the MemoryShape PAS per protocol version dated August 12, 2012. Mentor must report results of these explant analyses in the post-approval study Annual Report.

Mentor also agrees to participate as a stakeholder in developing the National Breast Implants Registry and to contribute data from their MemoryShape US Post-Approval Study to the Registry upon its implementation. Please be advised that because the establishment of the National Breast Implants Registry is currently in progress, this condition of approval will be labeled as "Study Pending" upon further notification from the FDA. Under this agreement, Mentor must submit interim reports every 6 months that include: (1) activities that they undertake for the development of the National Breast Implant Registry; (2) US sales data for the MemoryShape breast implants; and (3) US implant data for the MemoryShape breast implants.

Otherwise, Mentor's reporting requirements for the MemoryShape US-PAS are as follows:

On a quarterly basis, Mentor must submit a report to FDA that includes: (1) the number enrolled by subjects receiving studied device versus enrolled in comparison group; (2) the number enrolled by indication (primary augmentation, revision-augmentation, primary reconstruction, revision-reconstruction) for subjects receiving studied device; (3) the number enrolled by race/ethnicity; (4) the enrollment rates versus the stated goals; (5) the reason why eligible patients were not enrolled into the study; and (6) the follow-up rates versus the stated goals. FDA will inform Mentor when quarterly reports are no longer necessary.

In addition, every 6 months for the first 2 years and then annually, thereafter, Mentor is to submit a progress report that includes: (1) the status of patient enrollment as it compares to the stated goals; (2) the status of the race/ethnicity distribution as it compares to the stated goals; (3) detailed patient and device accounting; (4) the reasons why eligible patients were not enrolled into the study; (5) the follow-up rates versus the stated goals; and (6) a summary of findings for all study endpoints.

Mentor must update their patient and physician labeling to reflect 5 and 10-year MemoryShape PAS study findings, 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.

4. Breast Implant Case-Control Studies To Address Rare Disease Outcomes

In order to evaluate the rare endpoints, FDA approves Mentor's proposal to conduct case-controlled studies using data that is already collected in countries where the device has been on the market for years. Per Breast Implant Case-Control Studies To Address Rare Disease Outcomes protocols version dated September 11, 2012, the purpose of Breast Implant Case-Control Studies To Address Rare Disease Outcomes are to evaluate the association between MemoryShape Silicone-Filled Breast Implants and five rare disease outcomes (rare connective tissue diseases, rare neurological diseases, brain cancer, cervical/vulvar cancer and lymphoma). These studies will be conducted in Denmark, Germany and the United Kingdom and will enroll a total of 5,750 cases and 5,000 controls. For each of the five rare disease outcomes, 1,150 cases will be enrolled and

compared to the controls on the history of the implantation of Mentor silicone gel-filled breast implants.

On a quarterly basis, Mentor must submit a report to FDA that includes: (1) the number enrolled by cases and controls; (2) the enrollment rate versus the stated goal. FDA will inform Mentor when quarterly reports are no longer necessary. In addition, within 3 months of the completion of subject enrollment and data collection, Mentor must submit a final Breast Implant Case-Control Studies To Address Rare Disease Outcomes study report that includes the results and conclusions of these studies.

5. Focus Group Study

Per Focus Group Study protocol version dated September 11, 2012, the purpose of the Focus Group Study is to evaluate the effectiveness of the informed decision material intended to educate potential breast implant surgery patients about the risks, complications, and benefits associated with breast implants and breast implant surgery. This will involve an independent group obtaining responses from patients on the content of the approved labeling. Upon completion of the focus group study, Mentor must submit a Final Report of the focus group study findings and suggested revision of patient and physician labeling based on those findings.

6. Device Explant Analyses

In addition to the studies listed above, Mentor must conduct non-PAS Device Explant Analyses for all MemoryShape Breast Implants that are retrieved in the commercial setting outside the post-approval studies, as per explant analysis protocol version dated August 12, 2012. On an annual basis, Mentor must report the results of these Device Explant Analyses in the PMA Annual Reports.

Please be advised that the Post-Approval Study reports should be submitted separately for each study. Two copies for each study, identified as "PMA Post-Approval Study Report" and bearing the applicable PMA reference number, should be submitted to the address below. For more information on post-approval studies, see the FDA guidance document entitled, "Procedures for Handling Post-Approval Studies Imposed by PMA Order" (www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070974.htm#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.

Before making any change affecting the safety or effectiveness of the 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" (www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089274.htm).

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, 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 www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

In accordance with the recall requirements specified in 21 CFR 806.10, 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 www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm.

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 on the FDA CDRH Internet HomePage located at www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm. 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 copies of all approved labeling in final printed form. Final printed 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 printed labeling is identical to the labeling approved in draft form. If the final printed 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 in 6 copies, 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
PMA Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning this approval order, please contact Tajanay Ki at (301) 796-6970.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
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