



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Kristine Foss  
Vice President, Clinical and Regulatory Affairs  
Mentor Corporation  
201 Mentor Drive  
Santa Barbara, California 93111

**NOV 17 2006**

Re: P030053  
Mentor MemoryGel™ Silicone Gel-Filled Breast Implants (Moderate Profile Style 7000,  
High Profile Style 4000, and Moderate Plus Profile Style 8000)  
Filed: December 12, 2003  
Amended: January 16, 20, and 26, February 24, August 31, 2004; January 4 and 18,  
March 3, April 1, July 13, August 16 and 22, 2005; June 30 and October 3, 2006  
Procode: FTR

Dear Ms. Foss:

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 Mentor MemoryGel™ Silicone Gel-Filled Breast Implants. This device is indicated for breast augmentation for women at least 22 years old and for breast reconstruction for women of any age. 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 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 result 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 described below and in the "Conditions of Approval" (enclosed).

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that, to ensure the safe and effective use of the device, the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii), (1) insofar as the labeling specify the requirements that apply to the training of practitioners who may use the device as approved in this order and (2) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act. 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 Study and Adjunct Study investigators, after which these physicians must also have completed the training program in order to have access to the Mentor product.

In addition to the postapproval requirements outlined in the enclosure, you have agreed to the conditions of approval described in items 1 through 6 below.

1. Core Postapproval Study

You must continue your Core Study until all patients have completed their 10-year evaluation in order to assess the long-term clinical performance of your product. Data are to be collected via annual physician follow-up evaluations. The primary changes to the protocol from premarket to postapproval are that all non-MRI patients will have a MRI at years 6, 8, and 10 and that all patients who were explanted without replacement will be evaluated through 10 years, as per the protocol. You must also update your patient and physician labeling to reflect 5 and 10-year Core 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.

2. Large Postapproval Study

You must conduct the 10-year large postapproval study, as per the protocol that was submitted to FDA on September 26, 2006. This study, which will begin patient enrollment within 90 days of PMA approval, will be a separate study from the Core Study and will include 41,900 Mentor silicone gel patients and 1,000 saline-filled breast implant patients as the control group. The purpose of this study is to address specific issues for which the Core Study was not designed to fully answer, as well as to provide a real-world assessment of some endpoints. The endpoints include long-term local complications, connective tissue disease (CTD), CTD signs and symptoms, neurological disease, neurological signs and symptoms, offspring issues, reproductive issues, lactation issues, cancer, suicide, mammography issues, and MRI compliance and rupture results. Data are to be collected via annual patient questionnaires, either completed via the web, mail, or telephone. There will also be physician evaluations at years 1, 4-6, and 9-10 to collect local complication data. You must update your patient and physician labeling to reflect 5 and 10-year large postapproval 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.

On a quarterly basis, you must submit a report to FDA that includes: (1) the number enrolled by implant group (silicone versus saline); (2) the number enrolled by indication (primary augmentation, revision-augmentation, primary reconstruction, revision-reconstruction) and implant group; (3) the number enrolled by race/ethnicity and implant group; (4) the enrollment rate versus the stated goals; and (5) the follow-up rates versus the stated goals. FDA will inform you when quarterly reports are no longer necessary.

Every 6 months for the first 2 years and then annually, thereafter, you are 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) a summary of findings for all study endpoints; and (5) the reasons why eligible patients were not enrolled into the study.

### 3. Device Failure Studies

You must continue preclinical studies to further characterize the long-term modes and causes of failure of explanted retrieved devices for the 10-year duration of the large postapproval study. In addition, you must perform additional studies to address the following specific issues:

- further evaluation of iatrogenic failures to address issues raised by the April 2005 Panel
- the characterization of when surgical instrument damage occurs
- further evaluation and characterization of failures due to localized shell stress
- any correlation between surgical factors (e.g., incision size) and device rupture.

You must also update your patient and physician labeling to reflect any relevant findings.

### 4. Focus Group Study

You must complete a focus group study of the augmentation and reconstruction patient labeling. This will involve an independent group obtaining responses from patients on the format and content of the approved labeling. Upon completion of the focus group study, you must provide a supplement with a report of the focus group study findings and revised patient and physician labeling based on those findings.

### 5. Informed Decision Process

As part of your formal informed decision process, you must distribute your approved patient labeling. Both the physician and the patient are intended to sign designated sections in order to best assure that a patient has obtained the labeling in an adequate enough time prior to surgery to read it and has understood the risks and other information associated with the Mentor device. You must administer your approved survey to a random selection of 50 physicians on an annual basis to determine the success of this process and provide a summary of the survey findings to FDA. FDA will inform you when a survey summary is no longer necessary. In addition, you are to provide training on this process as part of your physician training program.

6. Mentor Adjunct Study

You must cease new enrollment into the Mentor Adjunct Study (P910037 and P910038) and continue follow-up of all currently-enrolled Mentor Adjunct Study patients through their 5-year evaluations. You are to report these data as part of annual reports for P030053.

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

CDRH does not evaluate information related to contract liability warranties, however you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws.

CDRH will notify the public of its decision to approve your PMA by making available 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 <http://www.fda.gov/cdrh/pmapage.html>. Written requests for this information can also be made to the Dockets Management Branch, (HFA-305), Food and Drug Administration, 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 requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

Failure to comply with any postapproval requirement constitutes a ground for withdrawal of approval of a PMA. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

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. The labeling will not routinely be reviewed by FDA staff when PMA applicants include with their submission of the final printed labeling 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 triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)  
Center for Devices and Radiological Health  
Food and Drug Administration  
9200 Corporate Blvd.  
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Mr. Stephen Rhodes at (240) 276-3638.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Donna-Bea Tillman". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Donna-Bea Tillman, Ph.D., M.P.A.

Director

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure