

27. Please provide a detailed table identifying all (a) design changes and (b) significant manufacturing process changes made to your device since your original 1991 PMA. Please include the date that each change was made and the rationale for the change. We are especially interested in any changes that were made to improve the reliability of the device.

27 Response:

A detailed table (see below) identifying all design changes and significant manufacturing process changes made to Mentor's gel-filled device since 1991 was prepared. This table also includes the date that each change was made as well as the rationale for the change. An exhaustive review of the complaint (PE) and non-conformance (NCMR) database on a lot-to-lot basis was performed to assess whether the changes identified had any significant effect on rupture rates. The assessment revealed that there were no significant changes observed in either the PE or NCMR databases as a result of any of the design and manufacturing process modifications.

Change	Effective Date	Justification
-----	-----	<p>Material Substitution: Dow Corning announced in January 1993 that it would withdraw Silastic silicone elastomer materials from the market as well as silicone materials associated with applications related to reproduction, contraception, obstetrics, or cosmetic surgery procedures. Following Dow Corning's withdrawal of implant grade silicone from the market, FDA developed a strategy to provide an orderly transition to new suppliers that would minimize the impact on medical device availability while assuring the safety and effectiveness of the medical devices. FDA announced the availability of a guidance entitled "Guidance for Manufacturers of Silicone Medical Devices Affected by Withdrawal of Dow Corning Silastic Materials" in the Federal Register on July 6, 1993 (58 FR 36207). The guidance described the procedures for manufacturers to follow in order to document that the alternate material is "not substantially different" from the materials described in an original 510(k) or PMA application. As a result of Dow Corning's withdrawal, Mentor repl----- This material is used in the manufacture of----- ----- ----- Its for both the raw materials and finished devices confirm that the material is "not substantially different" from the original material.</p>
----- -----	3/3/1995	<p>Material Substitution: Please refer to explanation above. As a result of Dow Corning's withdrawal from the ----- -----</p>

Change	Effective Date	Justification
Transferred manufacturing facility from Goleta, CA. to Irving, TX.	3/8/1995	Manufacturing Location Change: Device manufacturing transferred from Goleta, CA to Irving, TX. The methods, equipment and controls used in the manufacturing, processing, packaging and storage at both plant sites are basically the same.
Expanding In-Process Specifications and Testing to include Finished Device Specifications and Testing.	10/9/1997	Manufacturing Process Change: The purpose of developing a product specification is to describe the characteristics of Mentor's finished product gel filled breast prostheses, as well as their critical parts during the manufacturing process. Use of these specifications will be one way to assure that the gel filled breast implants produced at Mentor's Irving, TX. facility consistently meet an acceptable level of quality and that they continue to meet their device design specification. Manufacturing and Quality improvements were implemented, including more defined specifications and test procedures to assure more consistent in-process subassemblies and finished products in compliance with design specifications.
Mentor Low Bleed gel implant ----- -----	12/11/1998	Design Change: To ensure a more consistent shell thic----- ----- upper thickness specification for the shell top/radius and shell bottom were calculated using the data from the process qualification (HS33.980112.02C).
----- Low Bleed Gel implant.	12/11/1998	Design Change: To ensure a more consistent shell thic----- -----

Change	Effective Date	Justification
----- of product validated and approved.	8/30/1999	Manufacturing Process Change: ----- ied which allows for the reesterilization of product, when necessary. This change showed no impact on the product.
----- ----- -----	10/1/1999	Manufacturing Process Change: An historical record of approximately 1800 samples revealed that all relevant specifications met acceptance criteria. Based on this acceptance history and statistical -----
----- introduced	12/17/1999	Material Substitution: -----
Gel fill amount changes to meet ASTM requirements	8/31/2001	Manufacturing Process Change: These changes are being made to comply with both the ASTM-F703 and ISO-12180 requirements for gel device fill volumes.
Mentor High Profile gel implant re-introduced.	11/28/2001	New Product Introduction: To meet marketing demands a higher profile device is required. A High Profile was previously manufactured in Mentor's Goleta, CA facility. Qualifications were successfully completed.

Change	Effective Date	Justification
Changed the tensile strength for ----- ----- minimum ----- minimum	6/3/2003	Design Change: Report HS72.021216.01 documents testing of unfilled and gel filled moderate and high profile gel shells varying the incoming raw material tensile strength and shell thickness. The report concl----- ----- ----- assurance that Moderate and High Profile HTV shells will have break force values greater than the requirements of ASTM F703 (2.5 Lbs. minimum). Note: There was never any actual failure associated with this change. It was prompted by the fact that, if both materials were delivered within the then-current incoming material specification but at the lower limit of the modulus specification, a failure could theoretically result. This was a precautionary change to prevent this eventuality.
----- ----- ----- -----	6/20/2003	
Moderate Plus Profile device introduction	8/18/2003	New Product Introduction: To meet marketing demands for a more comprehensive product offering the Moderate Plus Profile was added to the product family. Qualifications were successfully completed.