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**Mentor Corporation PMA P030053 Silicone Gel-Filled Breast Implants  
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**Data/Information Presentation**

**Bolded information is included on CD.** Non-bolded information was submitted to FDA but is not included on the CD because FDA considered it unnecessary as it is either covered by the FDA Panel memo, copies of published literature, or is replaced by an updated report/data that is included on the CD. No preclinical test report raw data are included on the CD.

<b>Device Description</b>	
P030053, Sec 1 - Description of devices subject to PMA approval (not included)	
<b>Manufacturing Information</b>	
M020018/M2	Includes: manufacturing procedures, quality control procedures, test methods and sterilization validation information (not included)
M020018/M2/A1	
<b>Design and Manufacturing Changes</b>	
P030053/A5 - Response to FDA question # 27	
<b>Biological/Toxicology Data</b>	
M020018/M1 - Biological/ Toxicology/ Data Submission Narrative	
M020018/M1/A1 - Responses to FDA's questions and corresponding attachments.	
A1 Attachments:	
Appendix 1 - Chemistry Testing Summary	
Appendix 3 - Carcinogenicity Study	
Appendix 4 - Mouse Lymphoma and Micronucleus Assay Data	
P030053/A 4 - Final Reproductive/Toxicology Report (Extended one-generation reproductive and developmental study) Note: the interim reproductive and developmental study is not included.	
P030053/A5 - Responses to FDA toxicology/biological questions #s 23-26	
A5 Attachment:	
Dr. Rodricks' Expert Review - Attachment 26	
<b>Chemistry Data</b>	
M020018/M3 - Chemistry Data Submission Narrative	
P030053/A 3 - M033 (Crosslinking) and CP275 (Extractables)	
P030053/A5 - Responses to FDA chemistry questions, #s 20-22 and related test reports.	
A5 Attachments:	
CP368 Pt Catalyst Valence - Attachment 24	
M043 IPA Wash - Attachment 25	

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<b>Physical/Mechanical Data</b>
<b>M020018/M4 - Physical/Mechanical Data Submission Narrative</b>
<b><u>Gel Cohesion Folder</u></b> <b>M020018/M4 Attachment:</b> <b>HS33.980925.03 – PPQ (Cohesivity testing is included in the PPQ report)</b>
<b><u>Fatigue Testing Folder</u></b> <b>M020018/M4 Attachment:</b> <b>M028 Cyclic Fatigue Testing (Original report dated 10/29/03)</b> <b>P030053/A5 Attachments:</b> <b>M016 Cyclic Fatigue Testing - Attachment 10 (Uniaxial and Biaxial fixtures)</b> <b>M028 Cyclic Fatigue Testing - Attachment 11 (Uniaxial fixture final report dated 8/24/04)</b> <b>HS222.040823.02 Crease Fold Testing - Attachment 17</b> <b>Email dated October 11, 2004 (Crease Fold Testing) Clarification regarding Mentor's crease folds testing study.</b>
<b><u>Gel Bleed Testing Folder</u></b> <b>M020018/M4 Attachments:</b> <b>HS72.030826.01 - Gel Bleed Test Report</b> <b>HS72.030826.01AdB - Gel Bleed Test Report addendum</b> <b>P030053/A5 Attachments:</b> <b>Response to FDA question on gel bleed # 26</b> <b>CP246 Gel Bleed – Attachment 28</b> <b>CP411 Gel Bleed – Attachment 29 (Determination of moisture, protein and fat)</b> <b>M054 Gel Loss - Attachment 30 (Updated gel loss report) The previous version is not included on the CD.</b>
<b>Shelf Life Data</b>
<b>P030053, Section 8.3 (not included)</b> <b>P030053/A5, Section 8.3 response to FDA question #28 (not included)</b> <b>P030053/A5 Section 8.3, Att. 31(not included)</b>

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<b>Modes and Causes of Rupture Data</b>
P030053, Section 8.1- (previous version of retrieval study is not included)
<b>P030053/A5 - Response to FDA question #3 pertaining to modes and causes of rupture</b>
<b><u>SEM and Optical Microscopy Studies Folder</u></b>
M050 SEM Brandon Study – Attachment 3
M051 SEM Brandon Study – Attachment 4
M052 Optical Microscopy – Attachment 5
HS220.020819.02AdA Retrieval – Attachment 6 (updated Retrieval report)
M053 Surgical Techniques – Attachment 15 (Statistical Analysis)
Dr. Brandon's Expert Report – Attachment 16
Email Dated November 10, 2004 (Clarification of failure modes in the SEM and optical microscopy studies (Attachments 4 and 5) and mitigation for these potential failure modes)
Email Dated November 11, 2004 (Clarification on number of iatrogenic failures (Attachment 5) and fatigue testing as a prediction for long-term failures (Attachment 11, which can be found in the mechanical section above).
<b><u>Physical Testing Folder</u></b>
M048 Physical Testing – Attachment 7
M049 Rupture Failure Analysis – Attachment 8
M044 In Vitro Biodegradation – Attachment 9
HS33.000111.01 Particle Specification – Attachment 12
HS222.040719.01 Bubble Specification – Attachment 13
M041 Iatrogenic Effects – Attachment 14

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<b>Clinical Data - Core Study</b>
<b>P030053 - Core Protocol</b>
P030053 - Original Core Clinical Study Report (not included)
<b>P030053/A5 - Responses to FDA questions #s: 1-2, 4, 5, 6-8, 9-16, 17, 18, 29-31</b> Responses to FDA questions #s: 1-2 Responses to FDA questions #: 4 Responses to FDA questions #: 5 Responses to FDA questions #s: 6-8 Responses to FDA questions #s: 9-16 Responses to FDA questions #: 17 Responses to FDA questions #: 18 Responses to FDA questions #s: 29-31 Attachment: A Attachment: B Attachment: C Attachment: D
<b>P030053/A5 - Updated 3-Year Core Study Report (Attachment 1 including data tables)</b> <b>A5 Attachments:</b> Attachment 18 (MRI Patient histories) Attachment 19 (Kaplan Meier Rates for Complications) Attachment 20 (CTD patient data) Attachment 21 (CTD - rheumatological symptoms Tables) Attachment 22 (GEE – GEE Model testing of the effect of age. Updated tables found in November 8, 2004 email replace these tables.)  Email Dated October 4, 2004 K-M 2 to 3 year Complication Rate comparison  Email Dated November 8, 2004 (Statistical Questions - Updated Table 11.12 from 22 Dec 2004 Email) (Updated GEE tables. The tables attached to this email replace the GEE tables in Attachment 22.)  Email Dated November 19, 2004 (MRI Tables 13.1 and 13.3.1 clarification) Email Dated November 29, 2004 (MRI Tables 13.1 and 13.3.1 clarification) Email Dated December 1, 2004 (MRI Tables 13.1 and 13.3.1 clarification)  Email Dated December 17, 2004 (updated CTD tables CTD (11.2, 11.3, 11.6, 11.7, 11.10, 11.11, 11.12)  Email Dated December 23, 2004 (CTD and GEE Tables Updated Tables 11.10, 11.11, and 11.12. The tables attached to this email replace the corresponding tables in the December 17, 2004 email.)  Email Dated January 3, 2005 (Updated Reoperation Tables 9.1 and 9.2)
<b>P030053/A6 - Psychological and Functional Benefits of Mentor's Silicone Gel-Filled Breast Implants</b>

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<b>Clinical Data - Adjunct Study</b>
P030053 - Adjunct Protocol P030053 - Original Adjunct Clinical Study Report (not included) P030053/A5 - Responses to FDA question #19 P030053/A 5, Attachment 23 - Updated 10 Year Annual Report
<b>Supplemental Clinical Data</b>
<b><u>Sharpe and Collis Long-Term Rupture Study:</u></b> P030053/A5 Sharpe and Collis Report – Attachment 2 (Long-term rupture rates (up to 14 years) from a UK clinical study conducted by Drs. Sharpe and Collis.)
Email Dated November 16, 2004 (Sharpe & Collis data clarification)
<b><u>Literature:</u></b> P030053 - Literature Section Submission (copies of citations are not included) P030053/A5 - Responses to FDA questions #s 32-33 - Additional literature summary pertaining to systemic and local health consequences associated with gel bleed (copies of citations are not included)
<b><u>Complaint Analysis:</u></b> P030053 - Complaint Analysis of Mentor's complaint database from 1984 to present
<b>Post Approval Conditions</b>
P030053, Section 7.0 Original information not included
P030053/A5 - Mentor's responses to FDA's questions pertaining to Post Approval conditions #37
<b>Post Approval Study:</b> Email dated September 30, 2004 (Post Approval Study)
Email dated October 5, 2004 (Post Approval Study)
Focus Group Protocol - Attachment 35
Patient Registry - Attachment 36
Physician Training Folder Physician Training - Attachment 38 (15 separate files)  Email dated November 30, 2004 (Physician Training)

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<b>Labeling</b>
P030053, Section 4 - Previous versions of physician and patient labeling are not included
P030053/A5 - Mentor responses to FDA's questions #s 34-36 not included <b>P030053/A5 - Labeling – physician labeling/package insert (PIDS)</b> <b>P030053/A5 - Labeling – Patient Brochure (Making an Informed Decision)</b>
<b>Summary of Safety and Effectiveness (SSED)</b>
P030053, Section 2 - (previous version of SSED not included) P030053/A5 - Mentor responses to FDA's questions # 38 not included <b>P030053/A5 - Updated SSED</b>