Kline, Cliff

From: Free, Donna
Sent: Monday, January 03, 2005 2:21 PM
To: Kline, Cliff
Subject: FW: CTD issues

-----Original Message-----
From: Free, Donna
Sent: Thursday, December 23, 2004 9:12 AM
To: 'Dawisha, Sahar'
Cc: Allen, Samie Niver; Michael, Maher; Kline, Cliff; Silverman, Phyllis M.
Subject: RE: CTD issues

Hi Sahar,

Here are the three tables from the 11 series that needed to be revised

Please note, in the tables where Core data are compared to Saline Breast PMA (SPS) data, SPS numbers may differ somewhat from those in the 2004 deficiency response because we merged SPS physical exam findings into SPS symptoms.

The submission of these tables completes all outstanding responses to your questions at this time

All of us here at Mentor wish you very Happy Holidays

Regards,

Donna

-----Original Message-----
From: Dawisha, Sahar [mailto:SXD@CDRH.FDA.GOV]
Sent: Thursday, December 23, 2004 7:10 AM
To: 'Free, Donna'; Dawisha, Sahar
Cc: Allen, Samie Niver; Michael, Maher; Kline, Cliff; Silverman, Phyllis M.
Subject: RE: CTD issues

Thanks Donna,

Any update on when the revised CTD tables (GEE and SPS vs Core gel) will be available?

Sahar

-----Original Message-----
From: Free, Donna [mailto:DFree@mentorcorp.com]
Sent: Wednesday, December 22, 2004 6:34 PM
To: 'Dawisha, Sahar'
Cc: Allen, Samie Niver; Michael, Maher; Kline, Cliff
Subject: RE: CTD issues

Sahar,

Please see our response below to the questions you posed 12/21/04. I hope this adequately

addresses these questions

Regards,

Donna

Could you provide the following relating to the CTD info:
1. A summary table which shows how the physical exam findings were merged with symptoms.

1 Response:
Below is the summary table that shows how the physical exam findings were merged with symptoms

Merged Rheumatological Symptoms and Physical Exam Findings

Rheumatological Symptoms	Rheumatological Physical Examination
Back pain/stiffness	
bruising with little or no injury - Severe	
chest pains - Severe	
Chronic cough	
Color changes on hands or feet with cold exposure	Raynaud's phenomenon
diarrhea, or constipation - Frequent, severe or persistent	
Difficulty swallowing	
Dryness of eyes, nose	
Dryness of mouth	
dryness of skin - Severe	
Excessive sensitivity to sun	
Exhaustion	
Fatigue	
fever - Persistent	
Frequent hives	
Generalized aching	
Hair loss - Unusual	Hair loss
Heart murmurs	
Heel pain	
Insomnia	
Jaw pain	
Joint pain	Joint Tenderness, Tinels or Phalen's signs
Joint swelling	Joint swellings (including wrists, digits, elbows, knees, ankles), swollen digits, erythema over knuckles, Joint deformities and flexion contracture (including boutonniere, ulnar drift, swan neck, trigger fingers), Non-tender lumps or nodules on elbows
Loss of appetite	
Loss of height	
Loss of weight without dieting	
muscle cramps - Frequent	
muscle pain - Frequent	Tenderness-insertion of deltoids, Muscle tenderness
Neck pain/stiffness	

Night sweats	
Numbness of feet	
Numbness of hands	
Open sores	
Pain on breathing	
Pain on swallowing or chewing	
Pain/grittiness in eyes	Painful eye redness with decreased vision, small pupils
rashes	Skin rashes, Bluish hue color on eyelids, Nail pitting
Redness of eyes	Painless eye redness
Ringing in ears	
Tender lumps/bumps	Tender lumps - tibia, Calcinosis over tibia, ulna, elbows
Tenderness of scalp	
Tightness of skin	Skin tightness, especially face and hands
Weakness	Muscle weakness (including head lift from supine position against gravity, inability to raise arms, inability to get out of chair)

2. A list of the individual CTD signs and/or symptoms which were used for the "Combined fatigue," "combined pain," and "combined fibromyalgia" groupings.

2. Response:
Below are two summary tables listing the individual CTD signs and/or symptoms which were used for the "combined fatigue," "combined pain." Please note, per FDA instructions in the 2004 Core Gel deficiency letter (question 7b) for a patient to be counted under the "combined fibromyalgia" groupings, she had to have at least one of the "combined fatigue" signs/symptoms and at least one of the "combined pain" signs/symptoms. Hence if she had one sign/symptom from both tables she was counted under "combined fibromyalgia."

Combined Fatigue - Individual CTD Signs and/or Symptoms

Rheumatological Symptoms	Rheumatological Physical Examination
Exhaustion	
Fatigue	
Weakness	Muscle weakness (including head lift from supine position against gravity, inability to raise arms, inability to get out of chair)

Combined Pain - Individual CTD Signs and/or Symptoms

Rheumatological Symptoms	Rheumatological Physical Examination
Back pain/stiffness	
Joint pain	Joint Tenderness, Tinels or Phalen's signs
Muscle cramps - Frequent	
Muscle pain - Frequent	Tenderness-insertion of deltoids, Muscle tenderness
Neck pain/stiffness	

-----Original Message-----
From: Dawisha, Sahar [mailto:SXD@CDRH.FDA.GOV]
Sent: Tuesday, December 21, 2004 10:03 AM
To: 'Free, Donna'; Kline, Cliff

Cc: Allen, Samie Niver; Michael, Maher
Subject: RE: CTD issues

Donna/Cliff,

Could you provide the following relating to the CTD info:

1 A summary table which shows how the physical exam findings were merged with symptoms.

2. A list of the individual CTD signs and/or symptoms which were used for the "Combined fatigue " "combined pain," and "combined fibromyalgia" groupings

Thanks!
Sahar

-----Original Message-----
From: Free, Donna [mailto:DFree@mentorcorp.com]
Sent: Friday, December 17, 2004 5:45 PM
To: 'Dawisha, Sahar'
Cc: Allen, Samie Niver; Silverman, Phyllis M.; Michael, Maher; Kline, Cliff
Subject: FW: CTD issues

Hi Sahar.

Please see our responses and the update of the tables you requested.

Have a great weekend!

Donna

-----Original Message-----
From: Kline, Cliff
Sent: Friday, December 17, 2004 11:07 AM
To: Free, Donna
Subject: RE: CTD issues

Could you incorporate the rheumatologic physical exam findings into the symptom categories and re-do the following:

1. All tables summarizing the symptom categories (e.g. Tables 11.2, 11.6 were the ones I could easily find).

1 Response:

Physical exam findings have been incorporated into all tables summarizing symptom categories (Tables 11.2, 11.3, and 11.7). The new column header is entitled "sign/symptom."

2. All statistical analyses/comparisons involving symptom categories (i.e. Table 11.10).

2 Response:

Table 11.10 compares Saline Prospective Study (SPS) symptom category results to those of the Core Study. This table has been updated by incorporating physical exam findings into symptom categories.

3. Compare the rheumatologic physical exam findings between the SPS and Core Gel (i.e. 11.11).

3 Response:

Table 11.11 compares SPS signs/symptoms results to those of the Core Study. This table has been updated by incorporating physical exam findings with the symptoms.

4. Include the rheumatologic physical exam findings into the combined fatigue, combined pain, and combined fibro (as requested in deficiency 7.b.) and compare this to SPS.

4 Response:
All 11.x tables have has been updated to include the physical exam findings into the combined fields of fatigue, pain, and fibromyalgia.

5. Include the rheumatologic physical exam findings into the symptom categories and perform the GEE analysis for age.

5 Response:
Table 11.12 has been updated to incorporate physical exam findings into the symptom categories.

-----Original Message-----
From: Free, Donna
Sent: Wednesday, December 08, 2004 8:07 AM
To: Kline, Cliff
Subject: FW: CTD issues

Cliff,

Please review and provide responses.

Thanks

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.10

A COMPARISON BETWEEN COREGEL AND SPS OF CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYSTEM CATEGORY - FDA Item 7b(1)
RECONSTRUCTION PATIENTS

	36 Months after Implant Surgery (a)				
	SPS		CoreGel (b)		
Sign/System Category	Number with Sign/System Category	Estimated Proportion with Sign/System Category (c)	Number with Sign/System Category	Estimated Proportion with Sign/System Category (c)	P-value (d)
Skin and Appendages	30	0.1168	2	0.0124	0.0006
Muscle	62	0.2258	15	0.0763	0.0006
Joint	48	0.2017	19	0.0857	0.2283
CNS	44	0.1726	4	0.0214	0.0001
Gastrointestinal	26	0.1015	1	0.0084	0.0023
Body as a Whole	91	0.3498	19	0.0962	<0.0001
Metabolic and Nutritional	9	0.0462	1	0.0043	0.1220
Hearing and Vestibular	6	0.0247	1	0.0046	0.1719
Respiratory	6	0.0293	0	0.0000	0.0809
Platelet, Bleeding, Clotting Disorder	7	0.0303	1	0.0047	0.1149
Cardiovascular	3	0.0103	0	0.0000	0.1585
Vision	8	0.0282	2	0.0084	0.2458
Any of the Above	138	0.5025	44	0.2149	0.0004
Total Patients Assessed	416		251		

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_10.SAS
Creation Date, Time: 22DEC04 20:00

(a) Time from implant surgery to first occurrence of event.
(b) SPS does not have revision patients. Excludes CoreGel data on revision patients.
(c) Based on Kaplan-Meier estimates.
(d) p-value is from log-rank test of estimated proportion among patients in SPS versus CoreGel.
Note: Sign/System categories were reviewed and approved by the FDA for the SPS report.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.10

A COMPARISON BETWEEN COREGEL AND SPS OF CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYSTEM CATEGORY - FDA Item 7b(1)
OVERALL PATIENTS

	36 Months after Implant Surgery (a)				
	SPS		CoreGel (b)		
Sign/System Category	Number with Sign/System Category	Estimated Proportion with Sign/System Category (c)	Number with Sign/System Category	Estimated Proportion with Sign/System Category (c)	P-value (d)
Skin and Appendages	83	0.0683	12	0.0189	<0.0001
Muscle	206	0.1672	34	0.0496	<0.0001
Joint	105	0.0883	36	0.0494	0.0230
CNS	137	0.1146	24	0.0355	<0.0001
Gastrointestinal	73	0.0606	5	0.0078	<0.0001
Body as a Whole	277	0.2234	38	0.0536	<0.0001
Metabolic and Nutritional	24	0.0206	3	0.0046	0.0197
Hearing and Vestibular	25	0.0212	8	0.0116	0.1656
Respiratory	12	0.0105	2	0.0027	0.0953
Platelet, Bleeding, Clotting Disorder	21	0.0176	3	0.0045	0.0146
Cardiovascular	23	0.0181	1	0.0013	0.0010
Vision	25	0.0195	7	0.0091	0.0788
Any of the Above	467	0.3706	97	0.1337	<0.0001
Total Patients Assessed	1680		802		

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_10.SAS
Creation Date, Time: 22DEC04 20:00

(a) Time from implant surgery to first occurrence of event.
(b) SPS does not have revision patients. Excludes CoreGel data on revision patients.
(c) Based on Kaplan-Meier estimates.
(d) p-value is from log-rank test of estimated proportion among patients in SPS versus CoreGel.
Note: Sign/System categories were reviewed and approved by the FDA for the SPS report.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.11

A COMPARISON BETWEEN COREGEL AND SPS OF CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYMPTOM - FDA Item 7b(1)
AUGMENTATION PATIENTS

	36 Months after Implant Surgery				
	SPS (a)		CoreGel		
Sign/Symptom	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	P-value (c)
LOSS OF WEIGHT WITHOUT DIETING	15	0.0160	2	0.0044	0.0625
FATIGUE	91	0.0948	9	0.0177	<0.0001
INSOMNIA	61	0.0653	8	0.0153	0.0002
WEAKNESS	34	0.0368	4	0.0075	0.0043
EXHAUSTION	37	0.0388	5	0.0100	0.0017
JOINT SWELLING	19	0.0205	7	0.0141	0.4988
HEEL PAIN	8	0.0086	5	0.0108	0.8925
FREQUENT MUSCLE CRAMPS	28	0.0289	5	0.0100	0.0208
NUMBNESS OF FEET	14	0.0150	5	0.0100	0.4503
RINGING IN EARS	19	0.0201	7	0.0140	0.4246
PAIN/GRITTINESS IN EYES	8	0.0079	3	0.0055	0.5823
DRYNESS OF EYES/NOSE	30	0.0318	1	0.0019	0.0003
PAIN ON SWALLOWING OR CHEWING	5	0.0055	0	0.0000	0.0664
NECK PAIN/STIFFNESS	58	0.0619	9	0.0188	0.0001
PAIN ON BREATHING	3	0.0043	0	0.0000	0.2982
HEART MURMURS	20	0.0201	1	0.0018	0.0033
LOSS OF APPETITE	16	0.0174	1	0.0019	0.0292
PERSISTENT FEVER	1	0.0010	0	0.0000	0.5028
NIGHT SWEATS	33	0.0335	7	0.0143	0.0100
GENERALIZED ACHING	22	0.0231	5	0.0105	0.0889

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_11.SAS
Creation Date, Time: 22DEC04 16:49

(a) SPS does not have revision patients. Excludes CoreGel data on revision patients.
(b) Based on Kaplan-Meier estimates.
(c) p-value is from log-rank test of estimated proportion with symptom type among patients in SPS versus CoreGel.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.11

A COMPARISON BETWEEN COREGEL AND SPS OF CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYMPTOM - FDA Item 7b(1)
AUGMENTATION PATIENTS

	36 Months after Implant Surgery				
	SPS (a)		CoreGel		
Sign/Symptom	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	P-value (c)
LOSS OF HEIGHT	0	0.0000	0	0.0000	0.5241
JOINT PAIN	50	0.0532	13	0.0262	0.0188
FREQUENT MUSCLE PAIN	10	0.0105	3	0.0057	0.1242
NUMBNESS OF HANDS	26	0.0274	13	0.0266	0.5458
JAW PAIN	21	0.0209	0	0.0000	0.0006
OPEN SORES	1	0.0010	0	0.0000	0.4931
REDNESS OF EYES	9	0.0090	3	0.0063	0.3000
DRYNESS OF MOUTH	15	0.0156	1	0.0019	0.0213
BACK PAIN/STIFFNESS	72	0.0754	6	0.0114	<0.0001
SEVERE CHEST PAINS	1	0.0010	2	0.0037	0.2018
CHRONIC COUGH	4	0.0039	2	0.0038	0.6876
DIFFICULTY SWALLOWING	5	0.0059	0	0.0000	0.1660
FREQUENT,SEVERE DIARRHEA/CONSTIPATION	27	0.0280	3	0.0062	0.0053
SEVERE RASHES	4	0.0041	3	0.0056	0.8073
SEVERE DRYNESS OF SKIN	23	0.0247	3	0.0068	0.0278
TENDER LUMPS/BUMPS	8	0.0091	1	0.0019	0.0357
EXCESSIVE SENSITIVITY TO SUN	10	0.0106	0	0.0000	0.0258
COLOR CHANGES ON HANDS/FEET WITH COLD EX	24	0.0263	0	0.0000	0.0003
FREQUENT HIVES	3	0.0030	1	0.0020	0.2995
TIGHTNESS OF SKIN	0	0.0000	0	0.0000	0.5453

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_11.SAS Creation Date, Time: 22DEC04 16:49
(a) SPS does not have revision patients. Excludes CoreGel data on revision patients.
(b) Based on Kaplan-Meier estimates.
(c) p-value is from log-rank test of estimated proportion with symptom type among patients in SPS versus CoreGel.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.11

A COMPARISON BETWEEN COREGEL AND SPS OF CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYMPTOM - FDA Item 7b(1)
AUGMENTATION PATIENTS

	36 Months after Implant Surgery				
	SPS (a)		CoreGel		
Sign/Symptom	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	P-value (c)
UNUSUAL HAIR LOSS	27	0.0282	3	0.0069	0.0021
TENDERNESS OF SCALP	7	0.0069	0	0.0000	0.0485
SEVERE BRUISING WITH LITTLE OR NO INJURY	14	0.0147	2	0.0043	0.0606
COMBINED FATIGUE	119	0.1238	10	0.0195	<0.0001
COMBINED PAIN	161	0.1683	20	0.0391	<0.0001
COMBINED FIBROMYALGIA	79	0.0815	8	0.0152	<0.0001
Any of the Above	329	0.3336	53	0.1030	<0.0001
Total Patients Assessed	1264		551		

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_11.SAS
Creation Date, Time: 22DEC04 16:49

(a) SPS does not have revision patients. Excludes CoreGel data on revision patients.
(b) Based on Kaplan-Meier estimates.
(c) p-value is from log-rank test of estimated proportion with symptom type among patients in SPS versus CoreGel.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.11

A COMPARISON BETWEEN COREGEL AND SPS OF CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYMPTOM - FDA Item 7b(1)
RECONSTRUCTION PATIENTS

	36 Months after Implant Surgery				
	SPS (a)		CoreGel		
Sign/Symptom	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	P-value (c)
LOSS OF WEIGHT WITHOUT DIETING	9	0.0462	1	0.0043	0.1220
FATIGUE	42	0.1635	7	0.0371	0.0014
INSOMNIA	22	0.0833	4	0.0214	0.0231
WEAKNESS	22	0.0842	4	0.0215	0.0316
EXHAUSTION	25	0.1061	2	0.0090	0.0035
JOINT SWELLING	20	0.0796	10	0.0449	0.7548
HEEL PAIN	9	0.0354	2	0.0130	0.1865
FREQUENT MUSCLE CRAMPS	20	0.0760	8	0.0351	0.4258
NUMBNESS OF FEET	9	0.0379	0	0.0000	0.0402
RINGING IN EARS	6	0.0247	1	0.0046	0.1719
PAIN/GRITTINESS IN EYES	2	0.0071	2	0.0084	0.8091
DRYNESS OF EYES/NOSE	14	0.0535	2	0.0084	0.0504
PAIN ON SWALLOWING OR CHEWING	1	0.0034	0	0.0000	0.3643
NECK PAIN/STIFFNESS	24	0.0851	4	0.0299	0.0149
PAIN ON BREATHING	2	0.0095	0	0.0000	0.2758
HEART MURMURS	3	0.0103	0	0.0000	0.1585
LOSS OF APPETITE	10	0.0424	0	0.0000	0.0253
PERSISTENT FEVER	2	0.0069	0	0.0000	0.3415
NIGHT SWEATS	33	0.1353	5	0.0277	0.0029
GENERALIZED ACHING	17	0.0653	3	0.0130	0.0361

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_11 SAS
Creation Date, Time: 22DEC04 16:49

(a) SPS does not have revision patients. Excludes CoreGel data on revision patients.
(b) Based on Kaplan-Meier estimates.
(c) p-value is from log-rank test of estimated proportion with symptom type among patients in SPS versus CoreGel.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.11

A COMPARISON BETWEEN COREGEL AND SPS OF CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS OR PHYSICAL EXAMINATION FINDINGS BY STGN/SYMPTOM - FDA Item 7b(1)
RECONSTRUCTION PATIENTS

	36 Months after Implant Surgery				
	SPS (a)		CoreGel		
Sign/Symptom	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	P-value (c)
LOSS OF HEIGHT	6	0.0324	4	0.0175	0.9362
JOINT PAIN	39	0.1686	17	0.0798	0.4607
FREQUENT MUSCLE PAIN	11	0.0381	4	0.0175	0.1669
NUMBNESS OF HANDS	20	0.0845	0	0.0000	0.0019
JAW PAIN	3	0.0155	1	0.0084	0.7904
OPEN SORES	0	0.0000	0	0.0000	<0.0001
REDNESS OF EYES	7	0.0247	0	0.0000	0.0613
DRYNESS OF MOUTH	14	0.0675	0	0.0000	0.0094
BACK PAIN/STIFFNESS	20	0.0859	3	0.0127	0.0283
SEVERE CHEST PAINS	1	0.0035	0	0.0000	0.3849
CHRONIC COUGH	5	0.0233	0	0.0000	0.1304
DIFFICULTY SWALLOWING	2	0.0068	0	0.0000	0.2609
FREQUENT,SEVERE DIARRHEA/CONSTIPATION	17	0.0650	1	0.0084	0.0288
SEVERE RASHES	2	0.0173	0	0.0000	0.3920
SEVERE DRYNESS OF SKIN	16	0.0562	0	0.0000	0.0034
TENDER LUMPS/BUMPS	5	0.0174	1	0.0068	0.4259
EXCESSIVE SENSITIVITY TO SUN	3	0.0106	0	0.0000	0.1152
COLOR CHANGES ON HANDS/FEET WITH COLD EX	8	0.0344	0	0.0000	0.0546
FREQUENT HIVES	0	0.0000	0	0.0000	<0.0001
TIGHTNESS OF SKIN	4	0.0145	0	0.0000	0.1714

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_11.SAS
Creation Date, Time: 22DEC04 16:49

(a) SPS does not have revision patients. Excludes CoreGel data on revision patients.
(b) Based on Kaplan-Meier estimates.
(c) p-value is from log-rank test of estimated proportion with symptom type among patients in SPS versus CoreGel.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.11

A COMPARISON BETWEEN COREGEL AND SPS OF CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYMPTOM - FDA Item 7b(1)
RECONSTRUCTION PATIENTS

	36 Months after Implant Surgery				
	SPS (a)		CoreGel		
Sign/Symptom	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	P-value (c)
UNUSUAL HAIR LOSS	12	0.0498	2	0.0124	0.1110
TENDERNESS OF SCALP	2	0.0084	1	0.0043	0.9653
SEVERE BRUISING WITH LITTLE OR NO INJURY	7	0.0303	1	0.0047	0.1149
COMBINED FATIGUE	58	0.2172	10	0.0501	0.0002
COMBINED PAIN	77	0.2862	27	0.1344	0.0222
COMBINED FIBROMYALGIA	41	0.1439	8	0.0376	0.0050
Any of the Above	138	0.5025	44	0.2149	0.0004
Total Patients Assessed	416		251		

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_11.SAS Creation Date, Time: 22DEC04 16:49
(a) SPS does not have revision patients. Excludes CoreGel data on revision patients.
(b) Based on Kaplan-Meier estimates.
(c) p-value is from log-rank test of estimated proportion with symptom type among patients in SPS versus CoreGel.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.11

A COMPARISON BETWEEN COREGEL AND SPS OF CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYMPTOM - FDA Item 7b(1)
OVERALL PATIENTS

	36 Months after Implant Surgery				
	SPS (a)		CoreGel		
Sign/Symptom	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	P-value (c)
LOSS OF WEIGHT WITHOUT DIETING	24	0.0206	3	0.0046	0.0197
FATIGUE	133	0.1089	16	0.0229	<0.0001
INSOMNIA	83	0.0700	12	0.0168	<0.0001
WEAKNESS	56	0.0472	8	0.0111	0.0004
EXHAUSTION	62	0.0513	7	0.0099	<0.0001
JOINT SWELLING	39	0.0325	17	0.0235	0.5599
HEEL PAIN	17	0.0141	7	0.0112	0.3544
FREQUENT MUSCLE CRAMPS	48	0.0391	13	0.0177	0.0327
NUMBNESS OF FEET	23	0.0195	5	0.0072	0.0814
RINGING IN EARS	25	0.0212	8	0.0116	0.1656
PAIN/GRITTINESS IN EYES	10	0.0077	5	0.0064	0.7620
DRYNESS OF EYES/NOSE	44	0.0366	3	0.0039	<0.0001
PAIN ON SWALLOWING OR CHEWING	6	0.0051	0	0.0000	0.0405
NECK PAIN/STIFFNESS	82	0.0683	13	0.0207	<0.0001
PAIN ON BREATHING	5	0.0054	0	0.0000	0.1277
HEART MURMURS	23	0.0181	1	0.0013	0.0010
LOSS OF APPETITE	26	0.0222	1	0.0013	0.0020
PERSISTENT FEVER	3	0.0023	0	0.0000	0.2450
NIGHT SWEATS	66	0.0534	12	0.0177	0.0001
GENERALIZED ACHING	39	0.0318	8	0.0118	0.0085

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_11.SAS Creation Date, Time: 22DEC04 16:49
(a) SPS does not have revision patients. Excludes CoreGel data on revision patients.
(b) Based on Kaplan-Meier estimates.
(c) p-value is from log-rank test of estimated proportion with symptom type among patients in SPS versus CoreGel.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.11

A COMPARISON BETWEEN COREGEL AND SPS OF CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYMPTOM - FDA Item 7b(1)
OVERALL PATIENTS

	36 Months after Implant Surgery				
	SPS (a)		CoreGel		
Sign/Symptom	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	P-value (c)
LOSS OF HEIGHT	6	0.0055	4	0.0052	0.9946
JOINT PAIN	89	0.0753	30	0.0419	0.0310
FREQUENT MUSCLE PAIN	21	0.0169	7	0.0092	0.0436
NUMBNESS OF HANDS	46	0.0384	13	0.0195	0.0240
JAW PAIN	24	0.0190	1	0.0019	0.0009
OPEN SORES	1	0.0007	0	0.0000	0.4892
REDNESS OF EYES	16	0.0126	3	0.0046	0.0518
DRYNESS OF MOUTH	29	0.0249	1	0.0013	0.0005
BACK PAIN/STIFFNESS	92	0.0767	9	0.0120	<0.0001
SEVERE CHEST PAINS	2	0.0015	2	0.0026	0.7040
CHRONIC COUGH	9	0.0072	2	0.0027	0.2194
DIFFICULTY SWALLOWING	7	0.0065	0	0.0000	0.0716
FREQUENT,SEVERE DIARRHEA/CONSTIPATION	44	0.0358	4	0.0064	0.0004
SEVERE RASHES	6	0.0056	3	0.0040	0.5720
SEVERE DRYNESS OF SKIN	39	0.0323	3	0.0051	0.0004
TENDER LUMPS/BUMPS	13	0.0113	2	0.0030	0.0287
EXCESSIVE SENSITIVITY TO SUN	13	0.0110	0	0.0000	0.0059
COLOR CHANGES ON HANDS/FEET WITH COLD EX	32	0.0281	0	0.0000	<0.0001
FREQUENT HIVES	3	0.0023	1	0.0015	0.3010
TIGHTNESS OF SKIN	4	0.0032	0	0.0000	0.1417

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_11.SAS
Creation Date, Time: 22DEC04 16:49

(a) SPS does not have revision patients. Excludes CoreGel data on revision patients.
(b) Based on Kaplan-Meier estimates.
(c) p-value is from log-rank test of estimated proportion with symptom type among patients in SPS versus CoreGel.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.11

A COMPARISON BETWEEN COREGEL AND SPS OF CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYMPTOM - FDA Item 7b(1)
OVERALL PATIENTS

	36 Months after Implant Surgery				
	SPS (a)		CoreGel		
Sign/Symptom	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	P-value (c)
UNUSUAL HAIR LOSS	39	0.0324	5	0.0084	0.0006
TENDERNESS OF SCALP	9	0.0071	1	0.0013	0.0919
SEVERE BRUISING WITH LITTLE OR NO INJURY	21	0.0176	3	0.0045	0.0146
COMBINED FATIGUE	177	0.1442	20	0.0280	<0.0001
COMBINED PAIN	238	0.1947	47	0.0653	<0.0001
COMBINED FIBROMYALGIA	120	0.0965	16	0.0215	<0.0001
Any of the Above	467	0.3706	97	0.1337	<0.0001
Total Patients Assessed	1680		802		

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_11.SAS Creation Date, Time: 22DEC04 16:49
(a) SPS does not have revision patients. Excludes CoreGel data on revision patients.
(b) Based on Kaplan-Meier estimates.
(c) p-value is from log-rank test of estimated proportion with symptom type among patients in SPS versus CoreGel.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
In Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
AUGMENTATION PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
Sign/Symptom			
LOSS OF WEIGHT WITHOUT DIETING	Baseline	3/ 551 (0.54)	0.8622
	1 Year	3/ 530 (0.57)	.
	2 Year	2/ 524 (0.38)	.
	3 Year	2/ 404 (0.50)	.
FATIGUE	Baseline	1/ 551 (0.18)	0.0048
	1 Year	3/ 530 (0.57)	.
	2 Year	8/ 524 (1.53)	.
	3 Year	8/ 404 (1.98)	.
INSOMNIA	Baseline	6/ 551 (1.09)	0.1619
	1 Year	6/ 530 (1.13)	.
	2 Year	12/ 524 (2.29)	.
	3 Year	7/ 404 (1.73)	.
WEAKNESS	Baseline	2/ 551 (0.36)	0.2869
	1 Year	3/ 530 (0.57)	.
	2 Year	5/ 524 (0.95)	.
	3 Year	3/ 404 (0.74)	.
EXHAUSTION	Baseline	1/ 551 (0.18)	0.0379
	1 Year	2/ 530 (0.38)	.
	2 Year	5/ 524 (0.95)	.
	3 Year	5/ 404 (1.24)	.

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_12.SAS Creation Date, Time: 22DEC04 19:00

(1) p-value is from GEE model for the effect of the implant (year 1-3 visits versus baseline), adjusting for the age effect.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
AUGMENTATION PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
JOINT SWELLING	Baseline	1/ 551 (0.18)	0.0082
	1 Year	4/ 530 (0.75)	.
	2 Year	5/ 524 (0.95)	.
	3 Year	4/ 404 (0.99)	.
HEEL PAIN	Baseline	0/ 551 (0)	.
	1 Year	1/ 530 (0.19)	.
	2 Year	3/ 524 (0.57)	.
	3 Year	5/ 404 (1.24)	.
FREQUENT MUSCLE CRAMPS	Baseline	1/ 551 (0.18)	0.0241
	1 Year	2/ 530 (0.38)	.
	2 Year	5/ 524 (0.95)	.
	3 Year	4/ 404 (0.99)	.
NUMBNESS OF FEET	Baseline	0/ 551 (0)	.
	1 Year	1/ 530 (0.19)	.
	2 Year	4/ 524 (0.76)	
	3 Year	2/ 404 (0.50)	.
RINGING IN EARS	Baseline	5/ 551 (0.91)	0.9452
	1 Year	4/ 530 (0.75)	.
	2 Year	7/ 524 (1.34)	.
	3 Year	5/ 404 (1.24)	.
PAIN/GRITTINESS IN EYES	Baseline	1/ 551 (0.18)	0.3798

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_12.SAS

Creation Date, Time: 22DEC04 19:00

(1) p-value is from GEE model for the effect of the implant (year 1-3 visits versus baseline), adjusting for the age effect.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
In Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
AUGMENTATION PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
PAIN/GRITTINESS IN EYES	1 Year	3/ 530 (0.57)	.
	2 Year	3/ 524 (0.57)	.
	3 Year	2/ 404 (0.50)	.
DRYNESS OF EYES/NOSE	Baseline	3/ 551 (0.54)	0.4305
	1 Year	2/ 530 (0.38)	.
	2 Year	3/ 524 (0.57)	.
	3 Year	2/ 404 (0.50)	.
PAIN ON SWALLOWING OR CHEWING	Baseline	1/ 551 (0.18)	.
	1 Year	1/ 530 (0.19)	.
	2 Year	1/ 524 (0.19)	.
	3 Year	0/ 404 (0)	.
NECK PAIN/STIFFNESS	Baseline	3/ 551 (0.54)	0.0698
	1 Year	5/ 530 (0.94)	.
	2 Year	7/ 524 (1.34)	.
	3 Year	5/ 404 (1.24)	.
PAIN ON BREATHING	Baseline	0/ 551 (0)	.
	1 Year	0/ 530 (0)	.
	2 Year	0/ 524 (0)	.
	3 Year	0/ 404 (0)	.
HEART MURMURS	Baseline	9/ 551 (1.63)	0.2053
	1 Year	6/ 530 (1.13)	.

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_12.SAS Creation Date, Time: 22DEC04 19:00

(1) p-value is from GEE model for the effect of the implant (year 1-3 visits versus baseline), adjusting for the age effect.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11 12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
AUGMENTATION PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
HEART MURMURS	2 Year	6/ 524 (1.15)	.
	3 Year	3/ 404 (0.74)	.
LOSS OF APPETITE	Baseline	1/ 551 (0.18)	0.5364
	1 Year	1/ 530 (0.19)	.
	2 Year	2/ 524 (0.38)	.
	3 Year	1/ 404 (0.25)	.
PERSISTENT FEVER	Baseline	0/ 551 (0)	.
	1 Year	0/ 530 (0)	.
	2 Year	0/ 524 (0)	.
	3 Year	0/ 404 (0)	.
NIGHT SWEATS	Baseline	3/ 551 (0.54)	0.0956
	1 Year	4/ 530 (0.75)	.
	2 Year	6/ 524 (1.15)	.
	3 Year	6/ 404 (1.49)	.
GENERALIZED ACHING	Baseline	2/ 551 (0.36)	0.0641
	1 Year	2/ 530 (0.38)	.
	2 Year	5/ 524 (0.95)	.
	3 Year	5/ 404 (1.24)	.
LOSS OF HEIGHT	Baseline	0/ 551 (0)	.
	1 Year	0/ 530 (0)	.
	2 Year	0/ 524 (0)	.

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_12.SAS Creation Date, Time: 22DEC04 19:00

(1) p-value is from GEE model for the effect of the implant (year 1-3 visits versus baseline), adjusting for the age effect.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11 12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
AUGMENTATION PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
LOSS OF HEIGHT	3 Year	0/ 404 (0)	.
JOINT PAIN	Baseline	3/ 551 (0.54)	0.0016
	1 Year	4/ 530 (0.75)	.
	2 Year	12/ 524 (2.29)	.
	3 Year	12/ 404 (2.97)	.
FREQUENT MUSCLE PAIN	Baseline	2/ 551 (0.36)	0.2596
	1 Year	2/ 530 (0.38)	.
	2 Year	5/ 524 (0.95)	.
	3 Year	2/ 404 (0.50)	.
NUMBNESS OF HANDS	Baseline	2/ 551 (0.36)	0.0093
	1 Year	6/ 530 (1.13)	.
	2 Year	9/ 524 (1.72)	.
	3 Year	8/ 404 (1.98)	.
JAW PAIN	Baseline	5/ 551 (0.91)	
	1 Year	4/ 530 (0.75)	.
	2 Year	3/ 524 (0.57)	.
	3 Year	1/ 404 (0.25)	.
OPEN SORES	Baseline	0/ 551 (0)	.
	1 Year	0/ 530 (0)	.
	2 Year	0/ 524 (0)	.
	3 Year	0/ 404 (0)	.

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_12.SAS Creation Date, Time: 22DEC04 19:00

(1) p-value is from GEE model for the effect of the implant (year 1-3 visits versus baseline), adjusting for the age effect.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11 12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
AUGMENTATION PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
REDNESS OF EYES	Baseline	2/ 551 (0.36)	0.3632
	1 Year	2/ 530 (0.38)	.
	2 Year	4/ 524 (0.76)	.
	3 Year	4/ 404 (0.99)	.
DRYNESS OF MOUTH	Baseline	0/ 551 (0)	.
	1 Year	0/ 530 (0)	.
	2 Year	1/ 524 (0.19)	.
	3 Year	1/ 404 (0.25)	.
BACK PAIN/STIFFNESS	Baseline	7/ 551 (1.27)	0.8326
	1 Year	7/ 530 (1.32)	.
	2 Year	11/ 524 (2.10)	.
	3 Year	4/ 404 (0.99)	.
SEVERE CHEST PAINS	Baseline	0/ 551 (0)	.
	1 Year	1/ 530 (0.19)	.
	2 Year	2/ 524 (0.38)	.
	3 Year	1/ 404 (0.25)	.
CHRONIC COUGH	Baseline	1/ 551 (0.18)	.
	1 Year	0/ 530 (0)	.
	2 Year	2/ 524 (0.38)	.
	3 Year	2/ 404 (0.50)	.
DIFFICULTY SWALLOWING	Baseline	0/ 551 (0)	.

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_12.SAS Creation Date, Time: 22DEC04 19:00

(1) p-value is from GEE model for the effect of the implant (year 1-3 visits versus baseline), adjusting for the age effect.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
AUGMENTATION PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
DIFFICULTY SWALLOWING	1 Year	0/ 530 (0)	.
	2 Year	0/ 524 (0)	.
	3 Year	0/ 404 (0)	.
FREQUENT,SEVERE DIARRHEA/CONSTIPATION	Baseline	2/ 551 (0.36)	0.9470
	1 Year	2/ 530 (0.38)	.
	2 Year	1/ 524 (0.19)	
	3 Year	2/ 404 (0.50)	.
SEVERE RASHES	Baseline	1/ 551 (0.18)	.
	1 Year	2/ 530 (0.38)	.
	2 Year	3/ 524 (0.57)	.
	3 Year	0/ 404 (0)	.
SEVERE DRYNESS OF SKIN	Baseline	0/ 551 (0)	.
	1 Year	2/ 530 (0.38)	.
	2 Year	1/ 524 (0.19)	.
	3 Year	2/ 404 (0.50)	
TENDER LUMPS/BUMPS	Baseline	0/ 551 (0)	.
	1 Year	0/ 530 (0)	.
	2 Year	1/ 524 (0.19)	.
	3 Year	0/ 404 (0)	.
EXCESSIVE SENSITIVITY TO SUN	Baseline	0/ 551 (0)	.
	1 Year	0/ 530 (0)	.

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_12.SAS Creation Date, Time: 22DEC04 19:00

(1) p-value is from GEE model for the effect of the implant (year 1-3 visits versus baseline), adjusting for the age effect.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
AUGMENTATION PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
EXCESSIVE SENSITIVITY TO SUN	2 Year	0/ 524 (0)	.
	3 Year	0/ 404 (0)	.
COLOR CHANGES ON HANDS/FEET WITH COLD EXPOSURE	Baseline	4/ 551 (0.73)	0.3255
	1 Year	2/ 530 (0.38)	.
	2 Year	2/ 524 (0.38)	.
	3 Year	2/ 404 (0.50)	.
FREQUENT HIVES	Baseline	0/ 551 (0)	.
	1 Year	0/ 530 (0)	.
	2 Year	1/ 524 (0.19)	
	3 Year	0/ 404 (0)	.
TIGHTNESS OF SKIN	Baseline	1/ 551 (0.18)	.
	1 Year	1/ 530 (0.19)	.
	2 Year	0/ 524 (0)	.
	3 Year	0/ 404 (0)	.
UNUSUAL HAIR LOSS	Baseline	1/ 551 (0.18)	0.0918
	1 Year	1/ 530 (0.19)	.
	2 Year	2/ 524 (0.38)	.
	3 Year	3/ 404 (0.74)	.
TENDERNESS OF SCALP	Baseline	0/ 551 (0)	.
	1 Year	0/ 530 (0)	.
	2 Year	0/ 524 (0)	.

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_12.SAS Creation Date, Time: 22DEC04 19:00

(1) p-value is from GEE model for the effect of the implant (year 1-3 visits versus baseline), adjusting for the age effect.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
In Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
AUGMENTATION PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
TENDERNESS OF SCALP	3 Year	0/ 404 (0)	.
SEVERE BRUISING WITH LITTLE OR NO INJURY	Baseline	3/ 551 (0.54)	0.7481
	1 Year	3/ 530 (0.57)	.
	2 Year	2/ 524 (0.38)	.
	3 Year	2/ 404 (0.50)	.
COMBINED FATIGUE	Baseline	2/ 551 (0.36)	0.0278
	1 Year	4/ 530 (0.75)	.
	2 Year	9/ 524 (1.72)	.
	3 Year	8/ 404 (1.98)	.
COMBINED PAIN	Baseline	9/ 551 (1.63)	0.0179
	1 Year	12/ 530 (2.26)	.
	2 Year	20/ 524 (3.82)	.
	3 Year	14/ 404 (3.47)	.
COBINED FIBROMYALGIA	Baseline	1/ 551 (0.18)	0.0058
	1 Year	2/ 530 (0.38)	
	2 Year	9/ 524 (1.72)	.
	3 Year	7/ 404 (1.73)	.

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_12.SAS Creation Date, Time: 22DEC04 19:00

(1) p-value is from GEE model for the effect of the implant (year 1-3 visits versus baseline), adjusting for the age effect.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
AUGMENTATION PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
Sign/Symptom Category			
Skin and Appendages	Baseline	2/ 551 (0.36)	0.0156
	1 Year	5/ 530 (0.94)	.
	2 Year	6/ 524 (1.15)	.
	3 Year	5/ 404 (1.24)	.
Muscle	Baseline	11/ 551 (2.00)	0.0663
	1 Year	13/ 530 (2.45)	.
	2 Year	19/ 524 (3.63)	.
	3 Year	14/ 404 (3.47)	.
Joint	Baseline	3/ 551 (0.54)	0.0005
	1 Year	7/ 530 (1.32)	.
	2 Year	14/ 524 (2.67)	.
	3 Year	12/ 404 (2.97)	.
CNS	Baseline	8/ 551 (1.45)	0.0122
	1 Year	12/ 530 (2.26)	.
	2 Year	19/ 524 (3.63)	.
	3 Year	12/ 404 (2.97)	.
Gastrointestinal	Baseline	2/ 551 (0.36)	0.6254
	1 Year	2/ 530 (0.38)	.
	2 Year	2/ 524 (0.38)	.
	3 Year	3/ 404 (0.74)	.

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_12.SAS Creation Date, Time: 22DEC04 19:00

(1) p-value is from GEE model for the effect of the implant (year 1-3 visits versus baseline), adjusting for the age effect.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11 12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
AUGMENTATION PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
Body as a Whole	Baseline	12/ 551 (2.18)	0.1267
	1 Year	13/ 530 (2.45)	.
	2 Year	20/ 524 (3.82)	.
	3 Year	16/ 404 (3.96)	.
Metabolic and Nutritional	Baseline	3/ 551 (0.54)	0.8622
	1 Year	3/ 530 (0.57)	.
	2 Year	2/ 524 (0.38)	.
	3 Year	2/ 404 (0.50)	.
Hearing and Vestibular	Baseline	5/ 551 (0.91)	0.9452
	1 Year	4/ 530 (0.75)	.
	2 Year	7/ 524 (1.34)	.
	3 Year	5/ 404 (1.24)	.
Respiratory	Baseline	1/ 551 (0.18)	.
	1 Year	0/ 530 (0)	.
	2 Year	2/ 524 (0.38)	.
	3 Year	2/ 404 (0.50)	.
Platelet, Bleeding, Clotting Disorder	Baseline	3/ 551 (0.54)	0.7481
	1 Year	3/ 530 (0.57)	.
	2 Year	2/ 524 (0.38)	.
	3 Year	2/ 404 (0.50)	.
Cardiovascular	Baseline	9/ 551 (1.63)	0.2053

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_12.SAS

Creation Date, Time: 22DEC04 19:00

(1) p-value is from GEE model for the effect of the implant (year 1-3 visits versus baseline), adjusting for the age effect.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
In Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
AUGMENTATION PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
Cardiovascular	1 Year	6/ 530 (1.13)	.
	2 Year	6/ 524 (1.15)	.
	3 Year	3/ 404 (0.74)	.
Vision	Baseline	2/ 551 (0.36)	0.1170
	1 Year	4/ 530 (0.75)	.
	2 Year	6/ 524 (1.15)	.
	3 Year	5/ 404 (1.24)	.

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Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
RECONSTRUCTION PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p value (1)
Sign/Symptom			
LOSS OF WEIGHT WITHOUT DIETING	Baseline	1/ 251 (0.40)	.
	1 Year	0/ 240 (0)	.
	2 Year	1/ 230 (0.43)	.
	3 Year	0/ 121 (0)	.
FATIGUE	Baseline	5/ 251 (1.99)	0.3154
	1 Year	8/ 240 (3.33)	.
	2 Year	6/ 230 (2.61)	.
	3 Year	3/ 121 (2.48)	.
INSOMNIA	Baseline	10/ 251 (3.98)	0.1200
	1 Year	8/ 240 (3.33)	.
	2 Year	8/ 230 (3.48)	.
	3 Year	1/ 121 (0.83)	.
WEAKNESS	Baseline	2/ 251 (0.80)	0.9394
	1 Year	1/ 240 (0.42)	.
	2 Year	3/ 230 (1.30)	.
	3 Year	1/ 121 (0.83)	.
EXHAUSTION	Baseline	0/ 251 (0)	.
	1 Year	0/ 240 (0)	.
	2 Year	2/ 230 (0.87)	.
	3 Year	0/ 121 (0)	.

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_12.SAS Creation Date, Time: 22DEC04 19:00

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Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
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Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
RECONSTRUCTION PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
JOINT SWELLING	Baseline	9/ 251 (3.59)	0.2729
	1 Year	10/ 240 (4.17)	.
	2 Year	11/ 230 (4.78)	.
	3 Year	1/ 121 (0.83)	.
HEEL PAIN	Baseline	2/ 251 (0.80)	0.6368
	1 Year	2/ 240 (0.83)	.
	2 Year	3/ 230 (1.30)	.
	3 Year	1/ 121 (0.83)	.
FREQUENT MUSCLE CRAMPS	Baseline	2/ 251 (0.80)	0.1821
	1 Year	5/ 240 (2.08)	.
	2 Year	8/ 230 (3.48)	.
	3 Year	1/ 121 (0.83)	.
NUMBNESS OF FEET	Baseline	2/ 251 (0.80)	.
	1 Year	2/ 240 (0.83)	.
	2 Year	1/ 230 (0.43)	.
	3 Year	0/ 121 (0)	.
RINGING IN EARS	Baseline	3/ 251 (1.20)	0.4196
	1 Year	3/ 240 (1.25)	.
	2 Year	2/ 230 (0.87)	.
	3 Year	1/ 121 (0.83)	.
PAIN/GRITTINESS IN EYES	Baseline	0/ 251 (0)	.

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Table 11 12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
RECONSTRUCTION PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
PAIN/GRITTINESS IN EYES	1 Year	2/ 240 (0.83)	.
	2 Year	2/ 230 (0.87)	.
	3 Year	0/ 121 (0)	.
DRYNESS OF EYES/NOSE	Baseline	5/ 251 (1.99)	0.7403
	1 Year	6/ 240 (2.50)	.
	2 Year	7/ 230 (3.04)	.
	3 Year	1/ 121 (0.83)	.
PAIN ON SWALLOWING OR CHEWING	Baseline	0/ 251 (0)	.
	1 Year	0/ 240 (0)	.
	2 Year	0/ 230 (0)	.
	3 Year	0/ 121 (0)	.
NECK PAIN/STIFFNESS	Baseline	9/ 251 (3.59)	0.1293
	1 Year	6/ 240 (2.50)	.
	2 Year	6/ 230 (2.61)	.
	3 Year	3/ 121 (2.48)	.
PAIN ON BREATHING	Baseline	0/ 251 (0)	.
	1 Year	0/ 240 (0)	.
	2 Year	0/ 230 (0)	.
	3 Year	0/ 121 (0)	.
HEART MURMURS	Baseline	8/ 251 (3.19)	.
	1 Year	8/ 240 (3.33)	.

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Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
RECONSTRUCTION PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
HEART MURMURS	2 Year	6/ 230 (2.61)	.
	3 Year	1/ 121 (0.83)	.
LOSS OF APPETITE	Baseline	0/ 251 (0)	.
	1 Year	0/ 240 (0)	.
	2 Year	0/ 230 (0)	.
	3 Year	0/ 121 (0)	.
PERSISTENT FEVER	Baseline	0/ 251 (0)	.
	1 Year	0/ 240 (0)	.
	2 Year	0/ 230 (0)	.
	3 Year	0/ 121 (0)	.
NIGHT SWEATS	Baseline	9/ 251 (3.59)	0.2316
	1 Year	10/ 240 (4.17)	.
	2 Year	8/ 230 (3.48)	.
	3 Year	1/ 121 (0.83)	.
GENERALIZED ACHING	Baseline	3/ 251 (1.20)	.
	1 Year	3/ 240 (1.25)	.
	2 Year	6/ 230 (2.61)	.
	3 Year	0/ 121 (0)	.
LOSS OF HEIGHT	Baseline	1/ 251 (0.40)	0.0758
	1 Year	3/ 240 (1.25)	.
	2 Year	4/ 230 (1.74)	.

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GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
RECONSTRUCTION PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
LOSS OF HEIGHT	3 Year	2/ 121 (1.65)	.
JOINT PAIN	Baseline	6/ 251 (2.39)	0 0579
	1 Year	14/ 240 (5.83)	.
	2 Year	16/ 230 (6.96)	.
	3 Year	3/ 121 (2.48)	.
FREQUENT MUSCLE PAIN	Baseline	4/ 251 (1.59)	.
	1 Year	6/ 240 (2.50)	.
	2 Year	5/ 230 (2.17)	.
	3 Year	0/ 121 (0)	.
NUMBNESS OF HANDS	Baseline	2/ 251 (0.80)	.
	1 Year	1/ 240 (0.42)	.
	2 Year	1/ 230 (0.43)	.
	3 Year	0/ 121 (0)	.
JAW PAIN	Baseline	1/ 251 (0.40)	.
	1 Year	1/ 240 (0.42)	.
	2 Year	0/ 230 (0)	.
	3 Year	1/ 121 (0.83)	.
OPEN SORES	Baseline	0/ 251 (0)	.
	1 Year	0/ 240 (0)	.
	2 Year	0/ 230 (0)	.
	3 Year	0/ 121 (0)	.

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_12.SAS Creation Date, Time: 22DEC04 19:00

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GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
RECONSTRUCTION PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
REDNESS OF EYES	Baseline	1/ 251 (0.40)	.
	1 Year	1/ 240 (0.42)	.
	2 Year	2/ 230 (0.87)	.
	3 Year	0/ 121 (0)	.
DRYNESS OF MOUTH	Baseline	2/ 251 (0.80)	.
	1 Year	1/ 240 (0.42)	.
	2 Year	1/ 230 (0.43)	.
	3 Year	1/ 121 (0.83)	.
BACK PAIN/STIFFNESS	Baseline	8/ 251 (3.19)	0.4427
	1 Year	8/ 240 (3.33)	.
	2 Year	8/ 230 (3.48)	.
	3 Year	2/ 121 (1.65)	.
SEVERE CHEST PAINS	Baseline	0/ 251 (0)	.
	1 Year	0/ 240 (0)	.
	2 Year	0/ 230 (0)	.
	3 Year	0/ 121 (0)	.
CHRONIC COUGH	Baseline	0/ 251 (0)	.
	1 Year	0/ 240 (0)	.
	2 Year	0/ 230 (0)	.
	3 Year	0/ 121 (0)	.
DIFFICULTY SWALLOWING	Baseline	0/ 251 (0)	.

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Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
RECONSTRUCTION PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
DIFFICULTY SWALLOWING	1 Year	0/ 240 (0)	.
	2 Year	0/ 230 (0)	.
	3 Year	0/ 121 (0)	.
FREQUENT,SEVERE DIARRHEA/CONSTIPATION	Baseline	3/ 251 (1.20)	0.5114
	1 Year	2/ 240 (0.83)	.
	2 Year	3/ 230 (1.30)	.
	3 Year	1/ 121 (0.83)	.
SEVERE RASHES	Baseline	0/ 251 (0)	.
	1 Year	0/ 240 (0)	.
	2 Year	0/ 230 (0)	.
	3 Year	0/ 121 (0)	.
SEVERE DRYNESS OF SKIN	Baseline	1/ 251 (0.40)	.
	1 Year	1/ 240 (0.42)	.
	2 Year	1/ 230 (0.43)	.
	3 Year	0/ 121 (0)	
TENDER LUMPS/BUMPS	Baseline	0/ 251 (0)	.
	1 Year	0/ 240 (0)	.
	2 Year	1/ 230 (0.43)	.
	3 Year	0/ 121 (0)	.
EXCESSIVE SENSITIVITY TO SUN	Baseline	1/ 251 (0.40)	.
	1 Year	1/ 240 (0.42)	.

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Table 11 12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
RECONSTRUCTION PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
EXCESSIVE SENSITIVITY TO SUN	2 Year	1/ 230 (0.43)	.
	3 Year	0/ 121 (0)	.
COLOR CHANGES ON HANDS/FEET WITH COLD EXPOSURE	Baseline	4/ 251 (1.59)	.
	1 Year	4/ 240 (1.67)	.
	2 Year	4/ 230 (1.74)	.
	3 Year	2/ 121 (1.65)	.
FREQUENT HIVES	Baseline	1/ 251 (0.40)	.
	1 Year	1/ 240 (0.42)	.
	2 Year	0/ 230 (0)	.
	3 Year	0/ 121 (0)	.
TIGHTNESS OF SKIN	Baseline	0/ 251 (0)	.
	1 Year	0/ 240 (0)	.
	2 Year	0/ 230 (0)	.
	3 Year	0/ 121 (0)	.
UNUSUAL HAIR LOSS	Baseline	1/ 251 (0.40)	.
	1 Year	1/ 240 (0.42)	.
	2 Year	1/ 230 (0.43)	.
	3 Year	2/ 121 (1.65)	.
TENDERNESS OF SCALP	Baseline	1/ 251 (0.40)	0.9440
	1 Year	1/ 240 (0.42)	.
	2 Year	1/ 230 (0.43)	.

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GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
RECONSTRUCTION PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
TENDERNESS OF SCALP	3 Year	1/ 121 (0.83)	.
SEVERE BRUISING WITH LITTLE OR NO INJURY	Baseline	4/ 251 (1.59)	.
	1 Year	3/ 240 (1.25)	.
	2 Year	2/ 230 (0.87)	.
	3 Year	0/ 121 (0)	.
COMBINED FATIGUE	Baseline	7/ 251 (2.79)	0.5362
	1 Year	9/ 240 (3.75)	.
	2 Year	9/ 230 (3.91)	.
	3 Year	3/ 121 (2.48)	
COMBINED PAIN	Baseline	24/ 251 (9.56)	0.6397
	1 Year	29/ 240 (12.1)	.
	2 Year	27/ 230 (11.7)	.
	3 Year	6/ 121 (4.96)	.
COBINED FIBROMYALGIA	Baseline	5/ 251 (1.99)	0.7644
	1 Year	6/ 240 (2.50)	.
	2 Year	7/ 230 (3.04)	.
	3 Year	1/ 121 (0.83)	.

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GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
RECONSTRUCTION PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
Sign/Symptom Category			
Skin and Appendages	Baseline	3/ 251 (1.20)	0.7511
	1 Year	3/ 240 (1.25)	.
	2 Year	2/ 230 (0.87)	.
	3 Year	2/ 121 (1.65)	.
Muscle	Baseline	22/ 251 (8.76)	0.1411
	1 Year	21/ 240 (8.75)	.
	2 Year	19/ 230 (8.26)	.
	3 Year	5/ 121 (4.13)	.
Joint	Baseline	13/ 251 (5.18)	0.6752
	1 Year	20/ 240 (8.33)	.
	2 Year	21/ 230 (9.13)	.
	3 Year	3/ 121 (2.48)	.
CNS	Baseline	13/ 251 (5.18)	0.0593
	1 Year	10/ 240 (4.17)	.
	2 Year	10/ 230 (4.35)	.
	3 Year	1/ 121 (0.83)	.
Gastrointestinal	Baseline	3/ 251 (1.20)	0.5114
	1 Year	2/ 240 (0.83)	.
	2 Year	3/ 230 (1.30)	.
	3 Year	1/ 121 (0.83)	.

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Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
RECONSTRUCTION PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
Body as a Whole	Baseline	25/ 251 (9.96)	0.4781
	1 Year	27/ 240 (11.3)	.
	2 Year	26/ 230 (11.3)	.
	3 Year	8/ 121 (6.61)	.
Metabolic and Nutritional	Baseline	1/ 251 (0.40)	.
	1 Year	0/ 240 (0)	.
	2 Year	1/ 230 (0.43)	.
	3 Year	0/ 121 (0)	.
Hearing and Vestibular	Baseline	3/ 251 (1.20)	0.4196
	1 Year	3/ 240 (1.25)	.
	2 Year	2/ 230 (0.87)	.
	3 Year	1/ 121 (0.83)	.
Respiratory	Baseline	0/ 251 (0)	.
	1 Year	0/ 240 (0)	.
	2 Year	0/ 230 (0)	.
	3 Year	0/ 121 (0)	.
Platelet, Bleeding, Clotting Disorder	Baseline	4/ 251 (1.59)	.
	1 Year	3/ 240 (1.25)	.
	2 Year	2/ 230 (0.87)	.
	3 Year	0/ 121 (0)	.
Cardiovascular	Baseline	8/ 251 (3.19)	.

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GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
RECONSTRUCTION PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
Cardiovascular	1 Year	8/ 240 (3.33)	.
	2 Year	6/ 230 (2.61)	.
	3 Year	1/ 121 (0.83)	.
Vision	Baseline	1/ 251 (0.40)	.
	1 Year	3/ 240 (1.25)	.
	2 Year	4/ 230 (1.74)	.
	3 Year	0/ 121 (0)	.

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GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
REVISION PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
Sign/Symptom			
LOSS OF WEIGHT WITHOUT DIETING	Baseline	0/ 205 (0)	.
	1 Year	1/ 195 (0.51)	.
	2 Year	2/ 187 (1.07)	.
	3 Year	0/ 140 (0)	.
FATIGUE	Baseline	2/ 205 (0.98)	0.0188
	1 Year	6/ 195 (3.08)	.
	2 Year	12/ 187 (6.42)	.
	3 Year	4/ 140 (2.86)	.
INSOMNIA	Baseline	8/ 205 (3.90)	0.1977
	1 Year	8/ 195 (4.10)	.
	2 Year	6/ 187 (3.21)	.
	3 Year	2/ 140 (1.43)	.
WEAKNESS	Baseline	0/ 205 (0)	.
	1 Year	2/ 195 (1.03)	.
	2 Year	4/ 187 (2.14)	.
	3 Year	3/ 140 (2.14)	.
EXHAUSTION	Baseline	0/ 205 (0)	.
	1 Year	0/ 195 (0)	.
	2 Year	5/ 187 (2.67)	.
	3 Year	2/ 140 (1.43)	.

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Table 11 12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
REVISION PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
JOINT SWELLING	Baseline	2/ 205 (0.98)	0.4879
	1 Year	1/ 195 (0.51)	.
	2 Year	5/ 187 (2.67)	.
	3 Year	5/ 140 (3.57)	.
HEEL PAIN	Baseline	0/ 205 (0)	.
	1 Year	1/ 195 (0.51)	.
	2 Year	2/ 187 (1.07)	.
	3 Year	1/ 140 (0.71)	.
FREQUENT MUSCLE CRAMPS	Baseline	0/ 205 (0)	.
	1 Year	1/ 195 (0.51)	.
	2 Year	4/ 187 (2.14)	.
	3 Year	4/ 140 (2.86)	.
NUMBNESS OF FEET	Baseline	0/ 205 (0)	.
	1 Year	1/ 195 (0.51)	.
	2 Year	3/ 187 (1.60)	
	3 Year	3/ 140 (2.14)	.
RINGING IN EARS	Baseline	2/ 205 (0.98)	0.1225
	1 Year	5/ 195 (2.56)	.
	2 Year	4/ 187 (2.14)	.
	3 Year	3/ 140 (2.14)	.
PAIN/GRITTINESS IN EYES	Baseline	0/ 205 (0)	.

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_12.SAS Creation Date, Time: 22DEC04 19:00

(1) p-value is from GEE model for the effect of the implant (year 1-3 visits versus baseline), adjusting for the age effect.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
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Table 11 12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
REVISION PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
PAIN/GRITTINESS IN EYES	1 Year	0/ 195 (0)	.
	2 Year	0/ 187 (0)	.
	3 Year	0/ 140 (0)	.
DRYNESS OF EYES/NOSE	Baseline	6/ 205 (2.93)	.
	1 Year	4/ 195 (2.05)	.
	2 Year	3/ 187 (1.60)	.
	3 Year	0/ 140 (0)	.
PAIN ON SWALLOWING OR CHEWING	Baseline	0/ 205 (0)	.
	1 Year	0/ 195 (0)	.
	2 Year	2/ 187 (1.07)	.
	3 Year	1/ 140 (0.71)	.
NECK PAIN/STIFFNESS	Baseline	6/ 205 (2.93)	0.5630
	1 Year	7/ 195 (3.59)	.
	2 Year	4/ 187 (2.14)	.
	3 Year	3/ 140 (2.14)	.
PAIN ON BREATHING	Baseline	0/ 205 (0)	.
	1 Year	0/ 195 (0)	.
	2 Year	1/ 187 (0.53)	.
	3 Year	0/ 140 (0)	.
HEART MURMURS	Baseline	6/ 205 (2.93)	.
	1 Year	4/ 195 (2.05)	.

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_12.SAS Creation Date, Time: 22DEC04 19:00

(1) p-value is from GEE model for the effect of the implant (year 1-3 visits versus baseline), adjusting for the age effect.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
In Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
REVISION PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
HEART MURMURS	2 Year	3/ 187 (1.60)	.
	3 Year	0/ 140 (0)	.
LOSS OF APPETITE	Baseline	0/ 205 (0)	.
	1 Year	0/ 195 (0)	.
	2 Year	2/ 187 (1.07)	.
	3 Year	1/ 140 (0.71)	.
PERSISTENT FEVER	Baseline	0/ 205 (0)	.
	1 Year	0/ 195 (0)	.
	2 Year	0/ 187 (0)	.
	3 Year	0/ 140 (0)	.
NIGHT SWEATS	Baseline	4/ 205 (1.95)	.
	1 Year	6/ 195 (3.08)	.
	2 Year	0/ 187 (0)	.
	3 Year	0/ 140 (0)	.
GENERALIZED ACHING	Baseline	2/ 205 (0.98)	0.0421
	1 Year	3/ 195 (1.54)	.
	2 Year	8/ 187 (4.28)	.
	3 Year	5/ 140 (3.57)	.
LOSS OF HEIGHT	Baseline	1/ 205 (0.49)	.
	1 Year	1/ 195 (0.51)	.
	2 Year	2/ 187 (1.07)	.

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(1) p-value is from GEE model for the effect of the implant (year 1-3 visits versus baseline), adjusting for the age effect.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
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Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
REVISION PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
LOSS OF HEIGHT	3 Year	0/ 140 (0)	.
JOINT PAIN	Baseline	5/ 205 (2.44)	0.0700
	1 Year	9/ 195 (4.62)	.
	2 Year	12/ 187 (6.42)	.
	3 Year	9/ 140 (6.43)	.
FREQUENT MUSCLE PAIN	Baseline	1/ 205 (0.49)	0.2815
	1 Year	3/ 195 (1.54)	.
	2 Year	3/ 187 (1.60)	.
	3 Year	2/ 140 (1.43)	.
NUMBNESS OF HANDS	Baseline	6/ 205 (2.93)	0.6967
	1 Year	4/ 195 (2.05)	.
	2 Year	11/ 187 (5.88)	.
	3 Year	6/ 140 (4.29)	.
JAW PAIN	Baseline	0/ 205 (0)	.
	1 Year	1/ 195 (0.51)	.
	2 Year	0/ 187 (0)	.
	3 Year	0/ 140 (0)	.
OPEN SORES	Baseline	0/ 205 (0)	.
	1 Year	0/ 195 (0)	.
	2 Year	0/ 187 (0)	.
	3 Year	0/ 140 (0)	.

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Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
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Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
REVISION PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p value (1)
REDNESS OF EYES	Baseline	0/ 205 (0)	.
	1 Year	0/ 195 (0)	.
	2 Year	2/ 187 (1.07)	.
	3 Year	0/ 140 (0)	.
DRYNESS OF MOUTH	Baseline	1/ 205 (0.49)	0.7486
	1 Year	1/ 195 (0.51)	.
	2 Year	2/ 187 (1.07)	.
	3 Year	1/ 140 (0.71)	.
BACK PAIN/STIFFNESS	Baseline	3/ 205 (1.46)	0.3572
	1 Year	3/ 195 (1.54)	.
	2 Year	8/ 187 (4.28)	.
	3 Year	4/ 140 (2.86)	.
SEVERE CHEST PAINS	Baseline	0/ 205 (0)	.
	1 Year	0/ 195 (0)	.
	2 Year	0/ 187 (0)	
	3 Year	0/ 140 (0)	.
CHRONIC COUGH	Baseline	0/ 205 (0)	.
	1 Year	0/ 195 (0)	.
	2 Year	0/ 187 (0)	.
	3 Year	0/ 140 (0)	.
DIFFICULTY SWALLOWING	Baseline	0/ 205 (0)	.

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Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
REVISION PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
DIFFICULTY SWALLOWING	1 Year	0/ 195 (0)	.
	2 Year	2/ 187 (1.07)	.
	3 Year	1/ 140 (0.71)	.
FREQUENT,SEVERE DIARRHEA/CONSTIPATION	Baseline	3/ 205 (1.46)	0.3347
	1 Year	4/ 195 (2.05)	.
	2 Year	5/ 187 (2.67)	.
	3 Year	4/ 140 (2.86)	.
SEVERE RASHES	Baseline	0/ 205 (0)	.
	1 Year	0/ 195 (0)	.
	2 Year	0/ 187 (0)	.
	3 Year	0/ 140 (0)	.
SEVERE DRYNESS OF SKIN	Baseline	1/ 205 (0.49)	0.0758
	1 Year	2/ 195 (1.03)	.
	2 Year	5/ 187 (2.67)	.
	3 Year	2/ 140 (1.43)	.
TENDER LUMPS/BUMPS	Baseline	1/ 205 (0.49)	0.0504
	1 Year	3/ 195 (1.54)	.
	2 Year	5/ 187 (2.67)	.
	3 Year	3/ 140 (2.14)	.
EXCESSIVE SENSITIVITY TO SUN	Baseline	2/ 205 (0.98)	0.6012
	1 Year	2/ 195 (1.03)	.

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Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
REVISION PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
EXCESSIVE SENSITIVITY TO SUN	2 Year	3/ 187 (1.60)	.
	3 Year	2/ 140 (1.43)	.
COLOR CHANGES ON HANDS/FEET WITH COLD EXPOSURE	Baseline	2/ 205 (0.98)	.
	1 Year	3/ 195 (1.54)	.
	2 Year	4/ 187 (2.14)	.
	3 Year	3/ 140 (2.14)	.
FREQUENT HIVES	Baseline	0/ 205 (0)	.
	1 Year	0/ 195 (0)	.
	2 Year	1/ 187 (0.53)	.
	3 Year	0/ 140 (0)	.
TIGHTNESS OF SKIN	Baseline	0/ 205 (0)	.
	1 Year	0/ 195 (0)	.
	2 Year	0/ 187 (0)	.
	3 Year	0/ 140 (0)	.
UNUSUAL HAIR LOSS	Baseline	2/ 205 (0.98)	0.1627
	1 Year	3/ 195 (1.54)	.
	2 Year	4/ 187 (2.14)	.
	3 Year	4/ 140 (2.86)	.
TENDERNESS OF SCALP	Baseline	0/ 205 (0)	.
	1 Year	1/ 195 (0.51)	.
	2 Year	1/ 187 (0.53)	.

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Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
REVISION PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
TENDERNESS OF SCALP	3 Year	1/ 140 (0.71)	.
SEVERE BRUISING WITH LITTLE OR NO INJURY	Baseline	1/ 205 (0.49)	0.1265
	1 Year	2/ 195 (1.03)	.
	2 Year	4/ 187 (2.14)	.
	3 Year	3/ 140 (2.14)	.
COMBINED FATIGUE	Baseline	2/ 205 (0.98)	0.0159
	1 Year	7/ 195 (3.59)	.
	2 Year	12/ 187 (6.42)	.
	3 Year	4/ 140 (2.86)	.
COMBINED PAIN	Baseline	12/ 205 (5.85)	0.2210
	1 Year	15/ 195 (7.69)	
	2 Year	20/ 187 (10.7)	.
	3 Year	13/ 140 (9.29)	.
COBINED FIBROMYALGIA	Baseline	0/ 205 (0)	.
	1 Year	5/ 195 (2.56)	.
	2 Year	7/ 187 (3.74)	.
	3 Year	4/ 140 (2.86)	.

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Table 11 12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
REVISION PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
Sign/Symptom Category			
Skin and Appendages	Baseline	3/ 205 (1.46)	0.0152
	1 Year	5/ 195 (2.56)	.
	2 Year	9/ 187 (4.81)	.
	3 Year	6/ 140 (4.29)	.
Muscle	Baseline	9/ 205 (4.39)	0.4596
	1 Year	9/ 195 (4.62)	.
	2 Year	15/ 187 (8.02)	.
	3 Year	8/ 140 (5.71)	.
Joint	Baseline	6/ 205 (2.93)	0.0608
	1 Year	9/ 195 (4.62)	.
	2 Year	14/ 187 (7.49)	.
	3 Year	11/ 140 (7.86)	.
CNS	Baseline	13/ 205 (6.34)	0.7199
	1 Year	12/ 195 (6.15)	.
	2 Year	18/ 187 (9.63)	.
	3 Year	9/ 140 (6.43)	.
Gastrointestinal	Baseline	3/ 205 (1.46)	0.2411
	1 Year	4/ 195 (2.05)	.
	2 Year	6/ 187 (3.21)	.
	3 Year	4/ 140 (2.86)	.

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Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
REVISION PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
Body as a Whole	Baseline	17/ 205 (8.29)	0.6465
	1 Year	20/ 195 (10.3)	.
	2 Year	25/ 187 (13.4)	.
	3 Year	11/ 140 (7.86)	.
Metabolic and Nutritional	Baseline	0/ 205 (0)	.
	1 Year	1/ 195 (0.51)	.
	2 Year	2/ 187 (1.07)	.
	3 Year	0/ 140 (0)	.
Hearing and Vestibular	Baseline	2/ 205 (0.98)	0.1225
	1 Year	5/ 195 (2.56)	.
	2 Year	4/ 187 (2.14)	.
	3 Year	3/ 140 (2.14)	.
Respiratory	Baseline	0/ 205 (0)	.
	1 Year	0/ 195 (0)	.
	2 Year	1/ 187 (0.53)	.
	3 Year	0/ 140 (0)	.
Platelet, Bleeding, Clotting Disorder	Baseline	1/ 205 (0.49)	0.1265
	1 Year	2/ 195 (1.03)	.
	2 Year	4/ 187 (2.14)	.
	3 Year	3/ 140 (2.14)	.
Cardiovascular	Baseline	6/ 205 (2.93)	.

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Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
REVISION PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
Cardiovascular	1 Year	4/ 195 (2.05)	.
	2 Year	3/ 187 (1.60)	.
	3 Year	0/ 140 (0)	.
Vision	Baseline	0/ 205 (0)	.
	1 Year	0/ 195 (0)	.
	2 Year	2/ 187 (1.07)	.
	3 Year	0/ 140 (0)	.

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Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
OVERALL PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
Sign/Symptom			
LOSS OF WEIGHT WITHOUT DIETING	Baseline	4/1007 (0.40)	0.8250
	1 Year	4/ 965 (0.41)	.
	2 Year	5/ 941 (0.53)	.
	3 Year	2/ 665 (0.30)	.
FATIGUE	Baseline	8/1007 (0.79)	0.0002
	1 Year	17/ 965 (1.76)	.
	2 Year	26/ 941 (2.76)	.
	3 Year	15/ 665 (2.26)	.
INSOMNIA	Baseline	24/1007 (2.38)	0.6081
	1 Year	22/ 965 (2.28)	.
	2 Year	26/ 941 (2.76)	.
	3 Year	10/ 665 (1.50)	.
WEAKNESS	Baseline	4/1007 (0.40)	0.0727
	1 Year	6/ 965 (0.62)	.
	2 Year	12/ 941 (1.28)	.
	3 Year	7/ 665 (1.05)	.
EXHAUSTION	Baseline	1/1007 (0.10)	0.0057
	1 Year	2/ 965 (0.21)	.
	2 Year	12/ 941 (1.28)	.
	3 Year	7/ 665 (1.05)	.

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Table 11 12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
OVERALL PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
JOINT SWELLING	Baseline	12/1007 (1.19)	0.2166
	1 Year	15/ 965 (1.55)	.
	2 Year	21/ 941 (2.23)	.
	3 Year	10/ 665 (1.50)	.
HEEL PAIN	Baseline	2/1007 (0.20)	0.0138
	1 Year	4/ 965 (0.41)	.
	2 Year	8/ 941 (0.85)	.
	3 Year	7/ 665 (1.05)	.
FREQUENT MUSCLE CRAMPS	Baseline	3/1007 (0.30)	0.0009
	1 Year	8/ 965 (0.83)	.
	2 Year	17/ 941 (1.81)	.
	3 Year	9/ 665 (1.35)	.
NUMBNESS OF FEET	Baseline	2/1007 (0.20)	0.0278
	1 Year	4/ 965 (0.41)	.
	2 Year	8/ 941 (0.85)	
	3 Year	5/ 665 (0.75)	.
RINGING IN EARS	Baseline	10/1007 (0.99)	0.4562
	1 Year	12/ 965 (1.24)	.
	2 Year	13/ 941 (1.38)	.
	3 Year	9/ 665 (1.35)	.
PAIN/GRITTINESS IN EYES	Baseline	1/1007 (0.10)	0.1063

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Table 11 12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
OVERALL PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
PAIN/GRITTINESS IN EYES	1 Year	5/ 965 (0.52)	.
	2 Year	5/ 941 (0.53)	.
	3 Year	2/ 665 (0.30)	.
DRYNESS OF EYES/NOSE	Baseline	14/1007 (1.39)	0.0529
	1 Year	12/ 965 (1.24)	.
	2 Year	13/ 941 (1.38)	.
	3 Year	3/ 665 (0.45)	.
PAIN ON SWALLOWING OR CHEWING	Baseline	1/1007 (0.10)	0.5140
	1 Year	1/ 965 (0.10)	.
	2 Year	3/ 941 (0.32)	.
	3 Year	1/ 665 (0.15)	.
NECK PAIN/STIFFNESS	Baseline	18/1007 (1.79)	0.6353
	1 Year	18/ 965 (1.87)	.
	2 Year	17/ 941 (1.81)	.
	3 Year	11/ 665 (1.65)	.
PAIN ON BREATHING	Baseline	0/1007 (0)	.
	1 Year	0/ 965 (0)	.
	2 Year	1/ 941 (0.11)	.
	3 Year	0/ 665 (0)	.
HEART MURMURS	Baseline	23/1007 (2.28)	0.0006
	1 Year	18/ 965 (1.87)	.

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Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
OVERALL PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
HEART MURMURS	2 Year	15/ 941 (1.59)	.
	3 Year	4/ 665 (0.60)	.
LOSS OF APPETITE	Baseline	1/1007 (0.10)	0.2390
	1 Year	1/ 965 (0.10)	.
	2 Year	4/ 941 (0.43)	.
	3 Year	2/ 665 (0.30)	.
PERSISTENT FEVER	Baseline	0/1007 (0)	.
	1 Year	0/ 965 (0)	.
	2 Year	0/ 941 (0)	.
	3 Year	0/ 665 (0)	.
NIGHT SWEATS	Baseline	16/1007 (1.59)	0.6120
	1 Year	20/ 965 (2.07)	.
	2 Year	14/ 941 (1.49)	.
	3 Year	7/ 665 (1.05)	.
GENERALIZED ACHING	Baseline	7/1007 (0.70)	0.0309
	1 Year	8/ 965 (0.83)	.
	2 Year	19/ 941 (2.02)	.
	3 Year	10/ 665 (1.50)	.
LOSS OF HEIGHT	Baseline	2/1007 (0.20)	0.1929
	1 Year	4/ 965 (0.41)	.
	2 Year	6/ 941 (0.64)	.

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Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
OVERALL PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
LOSS OF HEIGHT	3 Year	2/ 665 (0.30)	.
JOINT PAIN	Baseline	14/1007 (1.39)	<.0001
	1 Year	27/ 965 (2.80)	.
	2 Year	40/ 941 (4.25)	.
	3 Year	24/ 665 (3.61)	.
FREQUENT MUSCLE PAIN	Baseline	7/1007 (0.70)	0.4310
	1 Year	11/ 965 (1.14)	.
	2 Year	13/ 941 (1.38)	.
	3 Year	4/ 665 (0.60)	.
NUMBNESS OF HANDS	Baseline	10/1007 (0.99)	0.0870
	1 Year	11/ 965 (1.14)	.
	2 Year	21/ 941 (2.23)	.
	3 Year	14/ 665 (2.11)	.
JAW PAIN	Baseline	6/1007 (0.60)	0.2939
	1 Year	6/ 965 (0.62)	.
	2 Year	3/ 941 (0.32)	.
	3 Year	2/ 665 (0.30)	.
OPEN SORES	Baseline	0/1007 (0)	.
	1 Year	0/ 965 (0)	.
	2 Year	0/ 941 (0)	.
	3 Year	0/ 665 (0)	.

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Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
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Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
OVERALL PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
REDNESS OF EYES	Baseline	3/1007 (0.30)	0.2081
	1 Year	3/ 965 (0.31)	.
	2 Year	8/ 941 (0.85)	.
	3 Year	4/ 665 (0.60)	.
DRYNESS OF MOUTH	Baseline	3/1007 (0.30)	0.9685
	1 Year	2/ 965 (0.21)	.
	2 Year	4/ 941 (0.43)	.
	3 Year	3/ 665 (0.45)	.
BACK PAIN/STIFFNESS	Baseline	18/1007 (1.79)	0.8497
	1 Year	18/ 965 (1.87)	.
	2 Year	27/ 941 (2.87)	.
	3 Year	10/ 665 (1.50)	.
SEVERE CHEST PAINS	Baseline	0/1007 (0)	.
	1 Year	1/ 965 (0.10)	.
	2 Year	2/ 941 (0.21)	.
	3 Year	1/ 665 (0.15)	.
CHRONIC COUGH	Baseline	1/1007 (0.10)	.
	1 Year	0/ 965 (0)	.
	2 Year	2/ 941 (0.21)	.
	3 Year	2/ 665 (0.30)	.
DIFFICULTY SWALLOWING	Baseline	0/1007 (0)	.

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Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
OVERALL PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
DIFFICULTY SWALLOWING	1 Year	0/ 965 (0)	.
	2 Year	2/ 941 (0.21)	.
	3 Year	1/ 665 (0.15)	.
FREQUENT,SEVERE DIARRHEA/CONSTIPATION	Baseline	8/1007 (0.79)	0.7543
	1 Year	8/ 965 (0.83)	.
	2 Year	9/ 941 (0.96)	.
	3 Year	7/ 665 (1.05)	.
SEVERE RASHES	Baseline	1/1007 (0.10)	.
	1 Year	2/ 965 (0.21)	.
	2 Year	3/ 941 (0.32)	.
	3 Year	0/ 665 (0)	.
SEVERE DRYNESS OF SKIN	Baseline	2/1007 (0.20)	0.0170
	1 Year	5/ 965 (0.52)	.
	2 Year	7/ 941 (0.74)	.
	3 Year	4/ 665 (0.60)	.
TENDER LUMPS/BUMPS	Baseline	1/1007 (0.10)	0.0291
	1 Year	3/ 965 (0.31)	.
	2 Year	7/ 941 (0.74)	.
	3 Year	3/ 665 (0.45)	.
EXCESSIVE SENSITIVITY TO SUN	Baseline	3/1007 (0.30)	0.9790
	1 Year	3/ 965 (0.31)	.

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Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1 3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
OVERALL PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
EXCESSIVE SENSITIVITY TO SUN	2 Year	4/ 941 (0.43)	.
	3 Year	2/ 665 (0.30)	.
COLOR CHANGES ON HANDS/FFFT WITH COLD EXPOSURE	Baseline	10/1007 (0.99)	0.8653
	1 Year	9/ 965 (0.93)	.
	2 Year	10/ 941 (1.06)	.
	3 Year	7/ 665 (1.05)	.
FREQUENT HIVES	Baseline	1/1007 (0.10)	.
	1 Year	1/ 965 (0.10)	.
	2 Year	2/ 941 (0.21)	.
	3 Year	0/ 665 (0)	.
TIGHTNESS OF SKIN	Baseline	1/1007 (0.10)	.
	1 Year	1/ 965 (0.10)	.
	2 Year	0/ 941 (0)	.
	3 Year	0/ 665 (0)	.
UNUSUAL HAIR LOSS	Baseline	4/1007 (0.40)	0.1382
	1 Year	5/ 965 (0.52)	.
	2 Year	7/ 941 (0.74)	.
	3 Year	9/ 665 (1.35)	.
TENDERNESS OF SCALP	Baseline	1/1007 (0.10)	0.5786
	1 Year	2/ 965 (0.21)	.
	2 Year	2/ 941 (0.21)	.

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GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
OVERALL PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
TENDERNESS OF SCALP	3 Year	2/ 665 (0.30)	.
SEVERE BRUISING WITH LITTLE OR NO INJURY	Baseline	8/1007 (0.79)	0.8377
	1 Year	8/ 965 (0.83)	.
	2 Year	8/ 941 (0.85)	.
	3 Year	5/ 665 (0.75)	.
COMBINED FATIGUE	Baseline	11/1007 (1.09)	0.0020
	1 Year	20/ 965 (2.07)	.
	2 Year	30/ 941 (3.19)	.
	3 Year	15/ 665 (2.26)	.
COMBINED PAIN	Baseline	45/1007 (4.47)	0.1366
	1 Year	56/ 965 (5.80)	.
	2 Year	67/ 941 (7.12)	.
	3 Year	33/ 665 (4.96)	.
COBINED FIBROMYALGIA	Baseline	6/1007 (0.60)	0.0006
	1 Year	13/ 965 (1.35)	.
	2 Year	23/ 941 (2.44)	.
	3 Year	12/ 665 (1.80)	.

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GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
OVERALL PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
Sign/Symptom Category			
Skin and Appendages	Baseline	8/1007 (0.79)	0.0049
	1 Year	13/ 965 (1.35)	.
	2 Year	17/ 941 (1.81)	.
	3 Year	13/ 665 (1.95)	.
Muscle	Baseline	42/1007 (4.17)	0.7591
	1 Year	43/ 965 (4.46)	.
	2 Year	53/ 941 (5.63)	.
	3 Year	27/ 665 (4.06)	.
Joint	Baseline	22/1007 (2.18)	0.0011
	1 Year	36/ 965 (3.73)	.
	2 Year	49/ 941 (5.21)	.
	3 Year	26/ 665 (3.91)	.
CNS	Baseline	34/1007 (3.38)	0.3976
	1 Year	34/ 965 (3.52)	.
	2 Year	47/ 941 (4.99)	.
	3 Year	22/ 665 (3.31)	.
Gastrointestinal	Baseline	8/1007 (0.79)	0.4881
	1 Year	8/ 965 (0.83)	.
	2 Year	11/ 941 (1.17)	.
	3 Year	8/ 665 (1.20)	.

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GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
OVERALL PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
Body as a Whole	Baseline	54/1007 (5.36)	0.5862
	1 Year	60/ 965 (6.22)	.
	2 Year	71/ 941 (7.55)	.
	3 Year	35/ 665 (5.26)	.
Metabolic and Nutritional	Baseline	4/1007 (0.40)	0.8250
	1 Year	4/ 965 (0.41)	.
	2 Year	5/ 941 (0.53)	.
	3 Year	2/ 665 (0.30)	.
Hearing and Vestibular	Baseline	10/1007 (0.99)	0.4562
	1 Year	12/ 965 (1.24)	.
	2 Year	13/ 941 (1.38)	.
	3 Year	9/ 665 (1.35)	.
Respiratory	Baseline	1/1007 (0.10)	.
	1 Year	0/ 965 (0)	.
	2 Year	3/ 941 (0.32)	.
	3 Year	2/ 665 (0.30)	.
Platelet, Bleeding, Clotting Disorder	Baseline	8/1007 (0.79)	0.8377
	1 Year	8/ 965 (0.83)	.
	2 Year	8/ 941 (0.85)	.
	3 Year	5/ 665 (0.75)	.
Cardiovascular	Baseline	23/1007 (2.28)	0.0006

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GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)
OVERALL PATIENTS

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
Cardiovascular	1 Year	18/ 965 (1.87)	.
	2 Year	15/ 941 (1.59)	.
	3 Year	4/ 665 (0.60)	.
Vision	Baseline	3/1007 (0.30)	0.0209
	1 Year	7/ 965 (0.73)	.
	2 Year	12/ 941 (1.28)	.
	3 Year	5/ 665 (0.75)	.

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