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)

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
Symptom Type			
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	1/1007 (0.10)	0.0085
	1 Year	3/ 965 (0.31)	.
	2 Year	8/ 941 (0.85)	.
	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)	.

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

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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)

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
JOINT SWELLING	Baseline	6/1007 (0.60)	0.1263
	1 Year	8/ 965 (0.83)	.
	2 Year	14/ 941 (1.49)	.
	3 Year	6/ 665 (0.90)	.
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	0/1007 (0)	.
	1 Year	4/ 965 (0.41)	.

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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.

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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)

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
PAIN/GRITTINESS IN EYES	2 Year	4/ 941 (0.43)	.
	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)	.
	2 Year	15/ 941 (1.59)	.
	3 Year	4/ 665 (0.60)	.

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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)

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
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)	.
	3 Year	2/ 665 (0.30)	.
JOINT PAIN	Baseline	13/1007 (1.29)	0.0002
	1 Year	24/ 965 (2.49)	.

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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)

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
JOINT PAIN	2 Year	35/ 941 (3.72)	.
	3 Year	22/ 665 (3.31)	.
FREQUENT MUSCLE PAIN	Baseline	5/1007 (0.50)	0.5295
	1 Year	10/ 965 (1.04)	.
	2 Year	10/ 941 (1.06)	.
	3 Year	2/ 665 (0.30)	.
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)	.
REDNESS OF EYES	Baseline	3/1007 (0.30)	0.4338
	1 Year	3/ 965 (0.31)	.
	2 Year	7/ 941 (0.74)	.
	3 Year	3/ 665 (0.45)	.

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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)

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
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)	.
	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)	.

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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)

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
FREQUENT,SEVERE DIARRHEA/CONSTIPATION	2 Year	9/ 941 (0.96)	.
	3 Year	7/ 665 (1.05)	.
SEVERE RASHES	Baseline	0/1007 (0)	.
	1 Year	1/ 965 (0.10)	.
	2 Year	2/ 941 (0.21)	.
	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)	.
	2 Year	4/ 941 (0.43)	.
	3 Year	2/ 665 (0.30)	.
COLOR CHANGES ON HANDS/FEET 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)	.

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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)

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
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	3/1007 (0.30)	0.0151
	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)	.
	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	8/1007 (0.79)	0.0002
	1 Year	17/ 965 (1.76)	

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Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
COMBINED FATIGUE	2 Year	26/ 941 (2.76)	.
	3 Year	15/ 665 (2.26)	.
COMBINED PAIN	Baseline	44/1007 (4.37)	0.2607
	1 Year	54/ 965 (5.60)	.
	2 Year	63/ 941 (6.70)	.
	3 Year	31/ 665 (4.66)	.
COMBINED FIBROMYALGIA	Baseline	5/1007 (0.50)	0.0011
	1 Year	9/ 965 (0.93)	.
	2 Year	19/ 941 (2.02)	.
	3 Year	12/ 665 (1.80)	.

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Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
Symptom Category			
Skin and Appendages	Baseline	7/1007 (0.70)	0.0006
	1 Year	13/ 965 (1.35)	.
	2 Year	17/ 941 (1.81)	.
	3 Year	13/ 665 (1.95)	.
Muscle	Baseline	41/1007 (4.07)	0.7863
	1 Year	43/ 965 (4.46)	.
	2 Year	51/ 941 (5 42)	.
	3 Year	26/ 665 (3.91)	.
Joint	Baseline	16/1007 (1.59)	0.0009
	1 Year	27/ 965 (2.80)	.
	2 Year	39/ 941 (4.14)	.
	3 Year	22/ 665 (3.31)	.
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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Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
Body as a Whole	Baseline	52/1007 (5.16)	0.5369
	1 Year	57/ 965 (5.91)	.
	2 Year	69/ 941 (7.33)	.
	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
	1 Year	18/ 965 (1.87)	.

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Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
Cardiovascular	2 Year	15/ 941 (1.59)	.
	3 Year	4/ 665 (0.60)	.
Vision	Baseline	3/1007 (0.30)	0.0396
	1 Year	7/ 965 (0.73)	.
	2 Year	11/ 941 (1.17)	.
	3 Year	4/ 665 (0.60)	.

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Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
Physical Examination Finding			
WEAK HEADLIFT	Baseline	0/1007 (0)	.
	1 Year	2/ 965 (0.21)	.
	2 Year	3/ 941 (0.32)	.
	3 Year	0/ 665 (0)	.
INABILITY TO RAISE ARMS	Baseline	1/1007 (0.10)	.
	1 Year	1/ 965 (0.10)	.
	2 Year	1/ 941 (0.11)	.
	3 Year	0/ 665 (0)	.
INABILITY TO GET OUT OF CHAIR	Baseline	0/1007 (0)	.
	1 Year	0/ 965 (0)	.
	2 Year	1/ 941 (0.11)	.
	3 Year	0/ 665 (0)	.
WRIST SWELLING	Baseline	0/1007 (0)	.
	1 Year	1/ 965 (0.10)	.
	2 Year	2/ 941 (0.21)	.
	3 Year	0/ 665 (0)	.
DIGITS SWELLING	Baseline	4/1007 (0.40)	0.0640
	1 Year	8/ 965 (0.83)	.
	2 Year	9/ 941 (0.96)	.
	3 Year	6/ 665 (0.90)	.

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Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
ELBOWS SWELLING	Baseline	2/1007 (0.20)	.
	1 Year	0/ 965 (0)	.
	2 Year	3/ 941 (0.32)	.
	3 Year	0/ 665 (0)	.
KNEES SWELLING	Baseline	0/1007 (0)	.
	1 Year	2/ 965 (0.21)	.
	2 Year	4/ 941 (0.43)	.
	3 Year	4/ 665 (0.60)	.
ANKLES SWELLING	Baseline	0/1007 (0)	
	1 Year	1/ 965 (0.10)	.
	2 Year	4/ 941 (0.43)	.
	3 Year	2/ 665 (0.30)	.
BOUTONNIERE	Baseline	0/1007 (0)	.
	1 Year	0/ 965 (0)	.
	2 Year	1/ 941 (0.11)	.
	3 Year	0/ 665 (0)	.
ULNAR DRIFT	Baseline	0/1007 (0)	.
	1 Year	0/ 965 (0)	.
	2 Year	0/ 941 (0)	.
	3 Year	0/ 665 (0)	.
SWAN NECK	Baseline	0/1007 (0)	.
	1 Year	0/ 965 (0)	.

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Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
SWAN NECK	2 Year	0/ 941 (0)	.
	3 Year	0/ 665 (0)	.
TRIGGER FINGERS	Baseline	0/1007 (0)	.
	1 Year	0/ 965 (0)	.
	2 Year	1/ 941 (0.11)	.
	3 Year	1/ 665 (0.15)	.
JOINT TENDERNESS	Baseline	2/1007 (0.20)	0.0039
	1 Year	5/ 965 (0.52)	.
	2 Year	15/ 941 (1.59)	.
	3 Year	10/ 665 (1.50)	.
GRIP STRENGTH AND MOTION-FINGER TO PALM CREASE	Baseline	0/1007 (0)	.
	1 Year	0/ 965 (0)	.
	2 Year	1/ 941 (0.11)	.
	3 Year	0/ 665 (0)	.
NECK MOTION-CHIN TO CHEST OR STERNUM	Baseline	1/1007 (0.10)	.
	1 Year	2/ 965 (0.21)	.
	2 Year	2/ 941 (0.21)	.
	3 Year	0/ 665 (0)	.
CHEST EXPANSION	Baseline	2/1007 (0.20)	.
	1 Year	0/ 965 (0)	.
	2 Year	0/ 941 (0)	.
	3 Year	0/ 665 (0)	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11_12.SAS Creation Date, Time: 05NOV04 10:37

(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)

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
OCCIPUT TO WALL	Baseline	0/1007 (0)	.
	1 Year	1/ 965 (0.10)	.
	2 Year	2/ 941 (0.21)	.
	3 Year	0/ 665 (0)	.
JAW MOTION	Baseline	0/1007 (0)	.
	1 Year	0/ 965 (0)	.
	2 Year	0/ 941 (0)	.
	3 Year	0/ 665 (0)	.
BACK MOTION	Baseline	0/1007 (0)	.
	1 Year	1/ 965 (0.10)	.
	2 Year	1/ 941 (0.11)	.
	3 Year	0/ 665 (0)	.
HAIR LOSS	Baseline	3/1007 (0.30)	0.6767
	1 Year	4/ 965 (0.41)	.
	2 Year	3/ 941 (0.32)	.
	3 Year	4/ 665 (0.60)	.
SKIN TIGHTNESS	Baseline	0/1007 (0)	.
	1 Year	0/ 965 (0)	.
	2 Year	0/ 941 (0)	.
	3 Year	0/ 665 (0)	.
RAYNAUD'S PHENOMENON	Baseline	2/1007 (0.20)	0.6128
	1 Year	1/ 965 (0.10)	.

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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)

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
RAYNAUD'S PHENOMENON	2 Year	2/ 941 (0.21)	.
	3 Year	1/ 665 (0.15)	.
CALCINOSIS OVER TIBIA,ULNA,ELBOWS	Baseline	0/1007 (0)	.
	1 Year	0/ 965 (0)	.
	2 Year	0/ 941 (0)	.
	3 Year	0/ 665 (0)	.
SWOLLEN DIGITS	Baseline	1/1007 (0.10)	0.0305
	1 Year	2/ 965 (0.21)	.
	2 Year	6/ 941 (0.64)	.
	3 Year	3/ 665 (0.45)	.
ERYTHEMA OVER KNUCKLES	Baseline	0/1007 (0)	.
	1 Year	0/ 965 (0)	.
	2 Year	0/ 941 (0)	.
	3 Year	0/ 665 (0)	.
BLUISH HUE COLOR ON EYELIDS	Baseline	0/1007 (0)	.
	1 Year	0/ 965 (0)	.
	2 Year	0/ 941 (0)	.
	3 Year	0/ 665 (0)	.
NON-TENDER LUMPS OR BUMPS ON ELBOWS	Baseline	0/1007 (0)	.
	1 Year	0/ 965 (0)	.
	2 Year	0/ 941 (0)	.
	3 Year	0/ 665 (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)

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
TENDER LUMPS-TIBIA	Baseline	0/1007 (0)	.
	1 Year	0/ 965 (0)	.
	2 Year	0/ 941 (0)	.
	3 Year	0/ 665 (0)	.
PAINLESS EYE REDNESS	Baseline	1/1007 (0.10)	0.1658
	1 Year	1/ 965 (0.10)	.
	2 Year	3/ 941 (0.32)	.
	3 Year	3/ 665 (0.45)	
PAINFUL EYE REDNESS WITH DECREASED VISION,SMAL	Baseline	1/1007 (0.10)	.
	1 Year	1/ 965 (0.10)	.
	2 Year	1/ 941 (0.11)	.
	3 Year	0/ 665 (0)	.
TENDERNESS-INSERTION OF DELTOIDS	Baseline	0/1007 (0)	.
	1 Year	0/ 965 (0)	.
	2 Year	1/ 941 (0.11)	.
	3 Year	0/ 665 (0)	.
MUSCLE TENDERNESS	Baseline	2/1007 (0.20)	0.9160
	1 Year	2/ 965 (0.21)	.
	2 Year	3/ 941 (0.32)	.
	3 Year	2/ 665 (0.30)	.
NAIL PITTINGS	Baseline	0/1007 (0)	.
	1 Year	0/ 965 (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)

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
NAIL PITTINGS	2 Year	0/ 941 (0)	.
	3 Year	0/ 665 (0)	.
TINELS OR PHALENS SIGNS	Baseline	0/1007 (0)	.
	1 Year	0/ 965 (0)	.
	2 Year	1/ 941 (0.11)	.
	3 Year	0/ 665 (0)	.
SKIN RASHES	Baseline	1/1007 (0.10)	
	1 Year	1/ 965 (0.10)	
	2 Year	2/ 941 (0.21)	.
	3 Year	0/ 665 (0)	.

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