TABLE 1

DEVICE CONFIGURATIONS FOR STUDIES A, B, C

	STUDY A	STUDY B	STUDY C
1. ACETABULAR COMPONENT			
MODULARTIY (Y/N)	YES	YES	YES
MATERIAL:			
a. BEARING INSERT	ASTM F-1537 CoCrMo	ASTM F-1537 CoCrMo	ASTM F-1537 CoCrMo
b. OUTER SHELL	ASTM F-136 Ti6Al4V	ASTM F-136 Ti6Al4V	ASTM F-136 Ti6Al4V
GRAIN SIZE	*ASTM 10-12	*ASTM 10-12	*ASTM 10-12
FEMORAL HEAD/BEARING INSERT CLEARANCE	radial clearance 20-40 microns	radial clearance 20-40 microns	radial clearance 25-75 microns
SURFACE ROUGHNESS	0.01 microns max	0.01 microns max	.05 microns
SPHERICITY	5 microns	5 microns	2 microns
INNER DIAMETER (MM)	28	28	28
2. FEMORAL HEAD COMPONENT			
MODULARTIY (Y/N)	YES	YES	YES
MATERIAL	ASTM F-1537 CoCrMo	ASTM F-1537 CoCrMo	ASTM F-799 CoCrMo
SURFACE ROUGHNESS	0.01 microns max	0.01 microns max	0.09 microns
SPHERICITY	12.5 microns	12.5 microns	<5 microns
GRAIN SIZE	*ASTM 10-12	*ASTM 10-12	*ASTM 10-12
HEAD DIAMETER (MM)	28	28	28
3. FEMORAL STEM COMPONENT(S)			
a. BRAND NAME	S-ROM FEMORAL PROSTHESIS	S-ROM FEMORAL PROSTHESIS	MALLORY/HEAD K853259
b. MATERIAL	ASTM F-620 or F-136 Ti6Al4V	ASTM F-620 or F-136 Ti6Al4V	ASTM F-620 or F-136 Ti6Al4V
c. BRAND NAME		ULTIMA FEMORAL PROSTHESIS	BIMETRIC K921224
d. MATERIAL		ASTM F-799 CoCroMo	ASTM F-620 or F-136 Ti6Al4V
e. BRAND NAME		ULTIMA LX FEMORAL PROSTHESIS	TAPERLOC K830313
f. MATERIAL		ASTM F-799 CoCroMo	ASTM F-620 or F-136 Ti6Al4V
g. BRAND NAME		ULTIMA TPS FEMORAL PROSTHESIS	INTERGRAL K921225
h. MATERIAL		ASTM F-799 CoCroMo	ASTM F-620 or F-136 Ti6Al4V
I. BRAND NAME		PFC FEMORAL PROSTHESIS	RANAWAT/BURSTEIN K921277
J. MATERIAL		ASTM F- 620 Ti6Al4V	ASTM F-799 CoCrMo

***Not a required manufacturing specification**

Key for Data Appraisal

1. Theoretical Due – all patients entered into clinical investigation. Theoretical follow-up due based on any patient who has reached his anniversary date for the time interval.

2. Expected Due – number theoretically due minus the number withdrawn.

3. Number Due in Interval – the number of patients who have reached their anniversary date, but have not exceeded the end point of the time interval and which no evaluation has been received to date (e.g., these patients are still retrievable for that time interval).

4. Number on File – the number of evaluations completed and reported by investigators.

5. Number Past Due – the number of evaluations not completed and/or reported by investigators that have moved beyond the end point for the time interval.

6. Number Withdrawn – the number of patients in which the device was removed, revised or have had the affected area amputated or are at a known end point and no longer can be followed (e.g., death).

7. Percent Missing – For IDE Annual Progress Reports, PMA applications and/or FDA post-approval reports, percent missing is calculated as:

$$\frac{\text{Past Due} + \text{Number Due in Interval}}{\text{Expected Due}}$$

SP80403K.DOC

Metal/Metal Hip Reclassification Petition
Distribution of Clinical Evaluations Across Time
Study A with Metal Liner Device Type
Table 2

Patient Status	Pre-Op Eval	6 Week Eval	6 Month Eval	12 Month Eval	24 Month Eval	36 Month Eval	48 Month Eval	60 Month Eval
Theoretical Due	219	219	203	179	109	25	0	0
Expected Due	219	219	203	179	109	25	0	0
Number Due in Interval	0	6	21	45	63	24	0	0
Number on File	219	195	149	112	40	1	0	0
Number Past Due	0	18	33	22	6	0	0	0
Number Lost to Followup	0	0	0	0	0	0	0	0
Percent Missing	0	8	18	16	13	0	0	0

Metal/Metal Hip Reclassification Petition 13:01 Friday, May 18, 2001
Distribution of Clinical Evaluations Across Time
Study A with Poly Liner Device Type
Table 2

Patient Status	Pre-Op Eval	6 Week Eval	6 Month Eval	12 Month Eval	24 Month Eval	36 Month Eval	48 Month Eval	60 Month Eval
Theoretical Due	206	206	189	162	100	20	0	0
Expected Due	206	206	188	161	100	20	0	0
Number Due in Interval	0	10	23	41	52	20	0	0
Number on File	206	185	137	104	46	0	0	0
Number Past Due	0	11	28	16	2	0	0	0
Number Lost to Followup	0	0	1	1	1	1	1	1
Percent Missing	0	6	17	13	4	0	0	0

x:\clinical\sasusers\mas\mom\MOMReclass\tables\cht-evsd.sas

Metal/Metal Hip Reclassification Petition 13:01 Friday, May 18, 2001

Distribution of Clinical Evaluations Across Time

Study B with Metal Liner Device Type

Table 2

Patient Status	Pre-Op Eval	6 Week Eval	6 Month Eval	12 Month Eval	24 Month Eval	36 Month Eval	48 Month Eval	60 Month Eval
Theoretical Due	87	87	87	87	87	60	0	0
Expected Due	87	87	87	87	87	60	0	0
Number Due in Interval	0	0	0	0	17	50	0	0
Number on File	87	85	72	67	37	10	0	0
Number Past Due	0	2	15	20	33	0	0	0
Number Lost to Followup	0	0	0	0	0	0	0	0
Percent Missing	0	2	17	23	47	0	0	0

x:\clinical\sasusers\mas\mom\MOMReclass\tables\cht-evsd.sas

Metal/Metal Hip Reclassification Petition 13:01 Friday, May 18, 2001
Distribution of Clinical Evaluations Across Time
Study C with Metal Liner Device Type
Table 2

Patient Status	Pre-Op Eval	6 Week Eval	6 Month Eval	12 Month Eval	24 Month Eval	36 Month Eval	48 Month Eval	60 Month Eval
Theoretical Due	97	97	97	94	72	45	23	0
Expected Due	97	97	97	94	72	45	23	0
Number Due in Interval	0	0	2	14	25	17	21	0
Number on File	97	0	85	67	34	20	2	0
Number Past Due	0	97	10	13	13	8	0	0
Number Lost to Followup	0	0	0	0	0	0	0	0
Percent Missing	0	100	11	16	28	29	0	0

x:\clinical\sasusers\mas\mom\MOMReclass\tables\cht-evsd.sas

Metal/Metal Hip Reclassification Petition 13:01 Friday, May 18, 2001
Distribution of Clinical Evaluations Across Time
Study C with Poly Liner Device Type
Table 2

Patient Status	Pre-Op Eval	6 Week Eval	6 Month Eval	12 Month Eval	24 Month Eval	36 Month Eval	48 Month Eval	60 Month Eval
Theoretical Due	97	97	97	87	66	44	17	0
Expected Due	97	97	97	87	66	44	17	0
Number Due in Interval	0	0	10	17	18	19	15	0
Number on File	97	0	72	53	37	22	2	0
Number Past Due	0	97	15	17	11	3	0	0
Number Lost to Followup	0	0	0	0	0	0	0	0
Percent Missing	0	100	17	24	23	12	0	0

x:\clinical\sasusers\mas\mom\MOMReclass\tables\cht-evsd.sas

Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Acetabular Cup
Table 3

11:56 Friday, May 18, 2001

---------- Study=A ----------

Device Type: Metal Liner

	Superior/Inferior Migration						Total
	Not Noted		0-5mm		> 5mm		
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	1	0.5	194	99.5		0.0	195
6 Mos		0.0	120	81.1	28	18.9	148
12 Mos	2	1.8	94	83.9	16	14.3	112
24 Mos		0.0	22	57.9	16	42.1	38
24+ Mos		0.0	23	59.0	16	41.0	39
36 Mos		0.0	1	100.0		0.0	1

x:\clinical\sasusers\mas\momreclass\tables\xr-mig.brook.sas

Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Acetabular Cup
Table 3

11:56 Friday, May 18, 2001

---------- Study=A ----------

Device Type: Poly Liner

	Superior/Inferior Migration						Total
	Not Noted		0-5mm		> 5mm		
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	3	1.6	180	98.4		0.0	183
6 Mos	2	1.4	107	75.9	32	22.7	141
12 Mos	2	1.9	81	76.4	23	21.7	106
24 Mos	2	4.2	31	64.6	15	31.3	48
24+ Mos	1	2.1	32	66.7	15	31.3	48
36 Mos							

x:\clinical\sasusers\mas\momreclass\tables\xr-mig.brook.sas

Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Acetabular Cup
Table 3

11:56 Friday, May 18, 2001

---------- Study=A ----------

Device Type: Metal Liner

	Medial/Lateral Migration						Total
	Not Noted		0-5mm		> 5mm		
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	1	0.5	194	99.5		0.0	195
6 Mos		0.0	129	87.2	19	12.8	148
12 Mos	2	1.8	98	87.5	12	10.7	112
24 Mos		0.0	28	73.7	10	26.3	38
24+ Mos		0.0	29	74.4	10	25.6	39
36 Mos		0.0	1	100.0		0.0	1

x:\clinical\sasusers\mas\momreclass\tables\xr-mig.brook.sas

Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Acetabular Cup
Table 3

11:56 Friday, May 18, 2001

---------- Study=A ----------

Device Type: Poly Liner

	Medial/Lateral Migration						Total
	Not Noted		0-5mm		> 5mm		
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	3	1.6	180	98.4		0.0	183
6 Mos	2	1.4	116	82.3	23	16.3	141
12 Mos	2	1.9	85	80.2	19	17.9	106
24 Mos	2	4.2	39	81.3	7	14.6	48
24+ Mos	1	2.1	40	83.3	7	14.6	48
36 Mos							

x:\clinical\sasusers\mas\momreclass\tables\xr-mig.brook.sas

Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Acetabular Cup
Table 3

11:56 Friday, May 18, 2001

---------- Study=B ----------

Device Type: Metal Liner

	Superior/Inferior Migration						Total
	Not Noted		0-5mm		> 5mm		
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	22	30.6	50	69.4		0.0	72
6 Mos	13	22.0	40	67.8	6	10.2	59
12 Mos	20	32.8	30	49.2	11	18.0	61
24 Mos	10	32.3	17	54.8	4	12.9	31
24+ Mos	11	29.7	22	59.5	4	10.8	37
36 Mos	3	33.3	6	66.7		0.0	9

x:\clinical\sasusers\mas\momreclass\tables\xr-mig.brook.sas

Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Acetabular Cup
Table 3

11:56 Friday, May 18, 2001

---------- Study=B ----------

Device Type: Metal Liner

	Medial/Lateral Migration						Total
	Not Noted		0-5mm		> 5mm		
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	22	30.6	50	69.4		0.0	72
6 Mos	13	22.0	40	67.8	6	10.2	59
12 Mos	20	32.8	28	45.9	13	21.3	61
24 Mos	10	32.3	15	48.4	6	19.4	31
24+ Mos	11	29.7	20	54.1	6	16.2	37
36 Mos	3	33.3	6	66.7		0.0	9

x:\clinical\sasusers\mas\momreclass\tables\xr-mig.brook.sas

Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Acetabular Cup
Table 3

11:56 Friday, May 18, 2001

---------- Study=C ----------

Device Type: Metal Liner

	Superior/Inferior Migration						Total
	Not Noted		0-5mm		> 5mm		
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	95	99.0	1	1.0		0.0	96
6 Mos	1	1.3	78	97.5	1	1.3	80
12 Mos		0.0	65	98.5	1	1.5	66
24 Mos		0.0	33	100.0		0.0	33
24+ Mos		0.0	36	100.0		0.0	36
36 Mos		0.0	15	100.0		0.0	15
48 Mos		0.0	1	100.0		0.0	1

x:\clinical\sasusers\mas\momreclass\tables\xr-mig.brook.sas

Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Acetabular Cup
Table 3

11:56 Friday, May 18, 2001

---------- Study=C ----------

Device Type: Poly Liner

	Superior/Inferior Migration						Total
	Not Noted		0-5mm		> 5mm		
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	95	100.0		0.0		0.0	95
6 Mos	1	1.5	65	98.5		0.0	66
12 Mos		0.0	52	100.0		0.0	52
24 Mos		0.0	31	100.0		0.0	31
24+ Mos		0.0	34	100.0		0.0	34
36 Mos		0.0	16	100.0		0.0	16
48 Mos		0.0	1	100.0		0.0	1

x:\clinical\sasusers\mas\momreclass\tables\xr-mig.brook.sas

Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Acetabular Cup
Table 3

11:56 Friday, May 18, 2001

---------- Study=C ----------

Device Type: Metal Liner

	Medial/Lateral Migration				Total
	Not Noted		0-5mm		
	#	Pct	#	Pct	#
Interval					
6 Week	95	99.0	1	1.0	96
6 Mos	1	1.3	79	98.8	80
12 Mos		0.0	66	100.0	66
24 Mos		0.0	33	100.0	33
24+ Mos		0.0	36	100.0	36
36 Mos		0.0	15	100.0	15
48 Mos		0.0	1	100.0	1

x:\clinical\sasusers\mas\momreclass\tables\xr-mig.brook.sas

Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Acetabular Cup
Table 3

11:56 Friday, May 18, 2001

---------- Study=C ----------

Device Type: Poly Liner

	Medial/Lateral Migration				Total
	Not Noted		0-5mm		
	#	Pct	#	Pct	#
Interval					
6 Week	95	100.0		0.0	95
6 Mos	1	1.5	65	98.5	66
12 Mos		0.0	52	100.0	52
24 Mos		0.0	31	100.0	31
24+ Mos		0.0	34	100.0	34
36 Mos		0.0	16	100.0	16
48 Mos		0.0	1	100.0	1

x:\clinical\sasusers\mas\momreclass\tables\xr-mig.brook.sas

---------- Study=A ----------

Device Type: Metal Liner

	Ectopic Ossification										Total
	Not Noted		None		Brooker I		Brooker II		Brooker III		
	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval											
6 Week	8	4.1	154	79.0	32	16.4	1	0.5		0.0	195
6 Mos	6	4.1	106	71.6	29	19.6	6	4.1	1	0.7	148
12 Mos	1	0.9	74	66.1	23	20.5	10	8.9	4	3.6	112
24 Mos		0.0	19	50.0	16	42.1	3	7.9		0.0	38
24+ Mos		0.0	19	48.7	16	41.0	4	10.3		0.0	39
36 Mos		0.0		0.0		0.0	1	100.0		0.0	1

Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Femoral Stem
Table 4

10:40 Friday, May 18, 2001

---------- Study=A ----------

Device Type: Poly Liner

	Ectopic Ossification										Total
	Not Noted		None		Brooker I		Brooker II		Brooker III		
	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval											
6 Week	10	5.5	145	79.2	22	12.0	6	3.3		0.0	183
6 Mos	6	4.3	92	65.2	32	22.7	11	7.8		0.0	141
12 Mos		0.0	71	67.0	22	20.8	9	8.5	4	3.8	106
24 Mos		0.0	23	47.9	16	33.3	7	14.6	2	4.2	48
24+ Mos		0.0	23	47.9	16	33.3	7	14.6	2	4.2	48
36 Mos											

x:\clinical\sasusers\mas\momreclass\tables\xr-mig.brook.sas

---------- Study=B ----------

Device Type: Metal Liner

	Ectopic Ossification										
	Not Noted		Brooker I		Brooker II		Brooker III		Brooker IV		Total
	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval											
6 Week	15	20.8	54	75.0	2	2.8		0.0	1	1.4	72
6 Mos	1	1.7	53	89.8	5	8.5		0.0		0.0	59
12 Mos	7	11.5	46	75.4	6	9.8	1	1.6	1	1.6	61
24 Mos	5	16.1	23	74.2	2	6.5	1	3.2		0.0	31
24+ Mos	6	16.2	28	75.7	3	8.1		0.0		0.0	37
36 Mos	2	22.2	6	66.7	1	11.1		0.0		0.0	9

---------- Study=C ----------

Device Type: Metal Liner

	Ectopic Ossification										
	Not Noted		None		Brooker I		Brooker II		Brooker IV		Total
	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval											
6 Week	95	99.0	1	1.0		0.0		0.0		0.0	96
6 Mos		0.0	66	82.5	10	12.5	4	5.0		0.0	80
12 Mos		0.0	50	75.8	11	16.7	5	7.6		0.0	66
24 Mos		0.0	26	78.8	4	12.1	3	9.1		0.0	33
24+ Mos		0.0	27	75.0	4	11.1	5	13.9		0.0	36
36 Mos		0.0	7	46.7	3	20.0	5	33.3		0.0	15
48 Mos		0.0		0.0	1	100.0		0.0		0.0	1

Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Femoral Stem
Table 4

10:40 Friday, May 18, 2001

---------- Study=C ----------

Device Type: Poly Liner

	Ectopic Ossification										
	Not Noted		None		Brooker I		Brooker II		Brooker IV		Total
	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval											
6 Week	95	100.0		0.0		0.0		0.0		0.0	95
6 Mos		0.0	51	77.3	8	12.1	6	9.1	1	1.5	66
12 Mos		0.0	37	71.2	9	17.3	6	11.5		0.0	52
24 Mos		0.0	20	64.5	8	25.8	3	9.7		0.0	31
24+ Mos	1	2.9	23	67.6	6	17.6	4	11.8		0.0	34
36 Mos	1	6.3	10	62.5	2	12.5	3	18.8		0.0	16
48 Mos		0.0	1	100.0		0.0		0.0		0.0	1

x:\clinical\sasusers\mas\momreclass\tables\xr-mig.brook.sas

MOM Reclassification Petition
Distribution of Device by Gender at 24+
Table 5

		Gender				Total
		F		M		
		Count	%	Count	%	Count
Study	Device Type					
A	Metal Liner	20	48.8	21	51.2	41
	Poly Liner	16	34.8	30	65.2	46
B	Metal Liner	17	39.5	26	60.5	43
	Poly Liner	.	.	.	.	.
C	Metal Liner	11	28.2	28	71.8	39
	Poly Liner	9	21.4	33	78.6	42

Analysis of Patient Age for Patients with a 24+

Table 6

The GLM Procedure

Class Level Information

Class	Levels	Values
STUDY	3	A B C
TRT	2	Metal Liner Poly Liner
SEX	2	F M

Number of observations 211

Analysis of Patient Age for Patients with a 24+
Table 6

The GLM Procedure

Dependent Variable: AGE

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	4	2099.81278	524.95319	4.31	0.0023
Error	206	25081.64694	121.75557		
Corrected Total	210	27181.45972			

R-Square	Coeff Var	Root MSE	AGE Mean
0.077252	21.04905	11.03429	52.42180

Source	DF	Type III SS	Mean Square	F Value	Pr > F
TRT	1	84.014029	84.014029	0.69	0.4071
STUDY	2	1969.705564	984.852782	8.09	0.0004
SEX	1	26.611859	26.611859	0.22	0.6406

Analysis of Patient Age for Patients with a 24+

Table 6

The GLM Procedure

Least Squares Means

TRT	AGE LSMEAN	Standard Error	HO:LSMEAN=0 Pr > |t|	HO:LSMean1= LSMean2 Pr > |t|
Metal Liner	52.5774403	1.0119424	<.0001	0.4071
Poly Liner	54.0005645	1.4114946	<.0001	

STUDY	AGE LSMEAN	Standard Error	Pr > |t|	LSMEAN Number
A	54.1281366	1.1917266	<.0001	1
B	56.9307114	1.9035312	<.0001	2
C	48.8081591	1.2927337	<.0001	3

Least Squares Means for effect STUDY

Pr > |t| for HO: LSMean(i)=LSMean(j)

Dependent Variable: AGE

i/j	1	2	3
1		0.2141	0.0023
2	0.2141		0.0004
3	0.0023	0.0004	

NOTE: To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

x:\clinical\sasusers\pev\mom510k\tables\glm.sas

Analysis of Patient Age for Patients with a 24+

Table 6

The GLM Procedure

Least Squares Means

SEX	AGE LSMEAN	Standard Error	H0:LSMEAN=0 Pr > |t|	H0:LSMean1= LSMean2 Pr > |t|
F	53.6693823	1.3675673	<.0001	0.6406
M	52.9086225	1.0012625	<.0001	

MOM Reclassification Petition
Analysis of Patient Age for Patients with a 24+
Table 6

The GLM Procedure

Level of TRT	N	AGE Mean	AGE Std Dev
Metal Liner	123	52.6260163	10.7049846
Poly Liner	88	52.1363636	12.3122048

Level of STUDY	N	AGE Mean	AGE Std Dev
A	87	54.1034483	12.2948604
B	43	56.1395349	9.0253120
C	81	48.6419753	10.4657879

Analysis of HHS Total Score at 24+

Table 7

The GLM Procedure

Class Level Information

Class	Levels	Values
STUDY	3	A B C
TRT	2	Metal Liner Poly Liner
SEX	2	F M

Number of observations 211

NOTE: Due to missing values, only 163 observations can be used in this analysis.

MOM Reclassification Petition 16:52 Thursday, May 17, 2001
Analysis of HHS Total Score at 24+
Table 7

The GLM Procedure

Dependent Variable: TOTAL

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	6	840.74866	140.12478	1.68	0.1299
Error	156	13031.90165	83.53783		
Corrected Total	162	13872.65031			

R-Square	Coeff Var	Root MSE	TOTAL Mean
0.060605	9.683485	9.139903	94.38650

Source	DF	Type III SS	Mean Square	F Value	Pr > F
TRT	1	162.7197083	162.7197083	1.95	0.1648
STUDY	2	261.8722838	130.9361419	1.57	0.2119
STUDY*TRT	1	85.8129703	85.8129703	1.03	0.3124
SEX	1	32.5271281	32.5271281	0.39	0.5335
AGE	1	13.8908407	13.8908407	0.17	0.6840

Source	DF	Type IV SS	Mean Square	F Value	Pr > F
TRT	1*	162.7197083	162.7197083	1.95	0.1648
STUDY	2*	328.7149201	164.3574601	1.97	0.1433
STUDY*TRT	1	85.8129703	85.8129703	1.03	0.3124

x:\clinical\sasusers\pev\mom510k\tables\glm.sas

MOM Reclassification Petition
Analysis of HHS Total Score at 24+
Table 7

The GLM Procedure

Dependent Variable: TOTAL

Source	DF	Type IV SS	Mean Square	F Value	Pr > F
SEX	1	32.5271281	32.5271281	0.39	0.5335
AGE	1	13.8908407	13.8908407	0.17	0.6840

* NOTE: Other Type IV Testable Hypotheses exist which may yield different SS.

MOM Reclassification Petition 16:52 Thursday, May 17, 2001
Analysis of HHS Total Score at 24+
Table 7

The GLM Procedure
Least Squares Means

TRT	TOTAL LSMEAN	Standard Error	Pr > |t|
Metal Liner	95.9513153	0.9975517	<.0001
Poly Liner	Non-est	.	.

STUDY	TOTAL LSMEAN	Standard Error	Pr > |t|	LSMEAN Number
A	93.1317302	1.0325218	<.0001	1
B	Non-est	.	.	2
C	94.2740242	1.3114062	<.0001	3

Least Squares Means for effect STUDY
Pr > |t| for H0: LSMean(i)=LSMean(j)

Dependent Variable: TOTAL

i/j	1	2	3
1		.	0.4890
2	.		.
3	0.4890	.	

NOTE: To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

x:\clinical\sasusers\pev\mom510k\tables\glm.sas

MOM Reclassification Petition
Analysis of HHS Total Score at 24+
Table 7

The GLM Procedure
Least Squares Means

SEX	TOTAL LSMEAN
F	Non-est
M	Non-est

STUDY	TRT	TOTAL LSMEAN	Standard Error	Pr > |t|	LSMEAN Number
A	Metal Liner	95.0563079	1.4832496	<.0001	1
A	Poly Liner	91.2071526	1.4294027	<.0001	2
B	Metal Liner	98.2141313	1.8491622	<.0001	3
C	Metal Liner	94.5835066	1.8142751	<.0001	4
C	Poly Liner	93.9645418	1.7716231	<.0001	5

Least Squares Means for effect STUDY*TRT
Pr > |t| for H0: LSMean(i)=LSMean(j)

Dependent Variable: TOTAL

i/j	1	2	3	4	5
1		0.0629	0.1843	0.8399	0.6360
2	0.0629		0.0026	0.1426	0.2214
3	0.1843	0.0026		0.1630	0.0982
4	0.8399	0.1426	0.1630		0.8005
5	0.6360	0.2214	0.0982	0.8005	

x:\clinical\sasusers\pev\mom510k\tables\glm.sas

The GLM Procedure
Least Squares Means

NOTE: To ensure overall protection level, only probabilities associated with pre-planned comparisons should be used.

MOM Reclassification Petition
Analysis of HHS Total Score at 24+
Table 7

16:52 Thursday, May 17, 2001

The GLM Procedure

Level of TRT	N	TOTAL Mean	TOTAL Std Dev	AGE Mean	AGE Std Dev
Metal Liner	90	95.8888889	7.9244245	52.0777778	11.2831064
Poly Liner	73	92.5342466	10.4284363	52.9726027	12.6347983

x:\clinical\sasusers\pev\mom510k\tables\glm.sas

Table 8
Dislocation and Loosening Rates

Early Metal/Metal Design Publications

Ref: No.	Devices	Dislocation	Dislocation (%)	Loose	Loose (%)
6	101	1	0.99%	3	2.97%
9	47	5	10.64%	0	0.00%
13	63	1	1.59%	31	49.21%
18	34	1	2.94%	13	38.24%
20	360	14	3.89%	7	1.94%
32	40	0	0.00%	16	40.00%
44	403	8	1.99%	27	6.70%
50	158	0	0.00%	0	0.00%
54	63	0	0.00%	5	7.94%
55	143	4	2.80%	18	12.59%
68	112	3	2.68%	7	6.25%
77	100	0	0.00%	20	20.00%
TOTALS	1624	37	2.27%	147	9.05%

Contemporary Metal/Metal Design Publications

Publication Ref: No.	Devices	Dislocation	Dislocation (%)	Loose	Loose (%)
15	54	2	3.70%	0	0.00%
23	74	3	4.05%	0	0.00%
75	100				

Unpublished Studies

Study	M/M Devices	Dislocation	Dislocation (%)	Loose	Loose (%)
A	219	1	0.45%	0	0.00%
B	87	3	3.45%	1	1.15%
C	63	2	3.17%	0	0.00%
TOTALS	403	6	1.49%	1	0.25%