



16/May/2012

Post market Surveillance and Risk Assessment Re-evaluation

Microstim MkIII
Viamed Product
Post market Surveillance
Risk Assessment
Stock References Review
Supplier Review
Sales Review
Country Sales Review
Stock Returns Review
Design Changes Review
User Manuals Review
Labels Review
Document Updates Review
Internal Issues Review
Clinical Information Review
FDA Incidents Review
Carried out by Derek Lamb on 16 / 05 / 12

Stock References Reviewed

Stock Reference	Description
2510000	Microstim DB3 - Supramaximal Nerve
2510001	Microstim DB3 - Supramaximal Nerve
2520000	Microstim DB3 - Patient Lead.

Comments on Stock references review:

no new part numbers

Supplier Information on Main and Component Parts

Stock Reference	Description	Supplier A/C	Supplier Name	Rating
2510000	Microstim DB3 - Supramaximal Nerve	00012164	Healthcare Technology Inter.	B
2520000	Microstim DB3 - Patient Lead.	00012164	Healthcare Technology Inter.	B

Comments on Suppliers:

supplier reviews upto date

Sales Information

Stock Reference	Description	2006	2007	2008	2009	2010	2011	2012
2510000	Microstim DB3 - Supramaximal Nerve	58	205	450	377	194	276	115
2510001	Microstim DB3 - Supramaximal Nerve					49		
2520000	Microstim DB3 - Patient Lead.	3	19	135	167	253	314	186

Comments on Sales Information:

sales are still holding, maybe slighty down on 2011

New Countries

Country	2006	2007	2008	2009	2010	2011	2012
AUS Australia				[X]	[X]	[X]	[X]
B Belgium			[X]		[X]		[X]
CAN Canada			[X]	[X]	[X]	[X]	[X]
CY Cyprus						[X]	
CZ Czech Republic			[X]				
DE Denmark			[X]				
EG Egypt				[X]		[X]	
FI Finland	[X]	[X]	[X]	[X]	[X]	[X]	[X]
G Germany	[X]						
GR Greece			[X]	[X]	[X]	[X]	
HK Hong Kong	[X]			[X]			
I Iran		[X]					
IN India	[X]	[X]	[X]				
IRE Ireland	[X]	[X]		[X]	[X]	[X]	[X]
J Japan			[X]				
KE Kenya		[X]	[X]			[X]	
KU Kuwait			[X]				
LEB Lebanon			[X]				
MA Malaysia			[X]		[X]		
MO Morocco						[X]	
NE Netherlands				[X]			
NG Nigera				[X]			
NO Norway			[X]				
NZ New Zealand			[X]				
OM Oman		[X]		[X]	[X]		
P Poland						[X]	[X]
PA Pakistan			[X]		[X]		[X]
PH Philippines							[X]
PO Portugal			[X]	[X]			
SA South Africa					[X]	[X]	
SAU Saudi Arabia			[X]		[X]	[X]	
SI Singapore					[X]	[X]	[X]
SWI Switzerland			[X]	[X]	[X]	[X]	
SY Syria		[X]					
T Turkey			[X]				
TUN Tunisia			[X]				
UAE U.A.E.		[X]	[X]	[X]	[X]		
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	[X]

Comments on Sales to Countries:

New sales to PH Philippines, still selling worldwide

Comments on Risks with Sales to Countries:

no new risks identified with selling to countries

Returns Information

Stock Reference	Fault	2006	2007	2008	2009	2010	2011	2012
2510000	Battery contacts tightened.		1					
2510000	Control knob spins						1	
2510000	Damaged during transit			1				
2510000	Dead							1
2510000	Dry joint					1		
2510000	Faulty patient cable					1		
2510000	Faulty patient cable replaced				4	2	5	
2510000	Intensity knob fitted				1	2		
2510000	Investigate					1		
2510000	Leads replaced		1			2	2	
2510000	LED replaced			1				
2510000	Modified to PN:2510001					39		
2510000	No output			2	1	3	3	
2510000	PCB assembly replaced				2	1		1
2510000	Tested OK			3		6		
2510000	Uneconomical to repair, service exchange				1			
2520000	No Fault Return to Stock							

Comments on Returns:

Return numbers still very low

Comments on Risks with Returns and Potential Re-work:

no risks with returns units.

Design Changes / Product Changes

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

Changed a capacitor. no effect to unit

Comments on Risks with Design Changes:

no risks identified with product changes

User Instructions

Showing Documents Filed in F 5 User Instructions

Document ID	Description	Date Added/Updated
9464	Microstim MkIII Instructions for Use / User Manual	18/10/11
5042	Microstim MkIII Instructions for Use / User Manual French	16/01/09
1059	Microstim Instructions for Use / User Manual Placement Diagram	31/10/06

Comments on User Instructions:

User manual has been updated to a PDF file

Comments on Risks User Instructions:

no risks found with user manual

Labels

Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
9463	Microstim MkIII Labels 250001 Appendix 1 page 20	18/10/11
9462	Microstim MkIII Labels 250001 box label	18/10/11
9169	No accessory labels	18/10/11
4795	Microstim MkIII Labels	20/10/08
4794	Microstim MkIII Labels	20/10/08
4793	Microstim MkIII Labels	20/10/08
4792	Microstim MkIII Labels	20/10/08
3301	Microstim MkIII Labels	26/02/08

Comments on Labels:

Comments on Risks Labels:

no risks associated with labels

Documentation Updates / Changes

Comments on Document Changes:

files brought upto date to the new essencial requirements,PDF`ed alot of old files

Comments on Risks with Document Changes:

no risks found with new documentation

Review of Issues

Number of Issues reviewed: 9

Issue ID	Subject
34317	SOR509 - Cromwell Hospital
32592	Returned Items SOR405
29695	Returned Items SOR78
27894	microstim lead
31087	Rotherhams comments re order lead times
32901	Microstim - web site edits
29831	New patient leads for use with Microstim DB3
34319	2510000 Ryan Swaine Sales Forecasts
34318	2510000 Ryan Swaine Sales Forecasts

Comments on Issues:

no comments on issues

Comments on Risks with Issues:

no risks found in any of the new issues

Review of online clinical reports

Do any of the Results indicate a Risk / Problem : No

Do any of the Results indicate outdated Technology : No

Comments on Clinical Search :

new book (refreshed version of old volume) The Clinical use of a New Nerve Stimulator. highlighting the usefulness of nerve stimulators.

shows the unit is not out of date and still useful

Review of online FDA Incident reports

Do any of the Results indicate a Risk / Problem : No

Do any of the Results indicate outdated Technology : No

Comments on Clinical Search :

No fda risks have been found