



24/May/2013

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
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Internal Issues Review
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FDA Incidents Review
Carried out by Derek Lamb on 24 / 05 / 13

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:

partnumber uptodate and correct

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 information has not changed, however units have not been purchased for 3 years,
accessory cables are still being purchased

Sales Information

Stock Reference	Description	2007	2008	2009	2010	2011	2012	2013
2510000	Microstim DB3 - Supramaximal Nerve	205	450	377	194	276	261	165
2510001	Microstim DB3 - Supramaximal Nerve				49			
2520000	Microstim DB3 - Patient Lead.	19	135	167	253	314	432	180

Comments on Sales Information:

units still selling, in consistant numbers

New Countries

Country	2007	2008	2009	2010	2011	2012	2013
AUS Australia			[X]	[X]	[X]	[X]	[X]
B Belgium		[X]		[X]		[X]	[X]
BA State of Bahrain							[X]
CAN Canada		[X]	[X]	[X]	[X]	[X]	[X]
CY Cyprus					[X]		
CZ Czech Republic		[X]					
DE Denmark		[X]					
EG Egypt			[X]		[X]		[X]
FI Finland	[X]	[X]	[X]	[X]	[X]	[X]	[X]
G Germany						[X]	[X]
GR Greece		[X]	[X]	[X]	[X]		[X]
HK Hong Kong			[X]				
I Iran	[X]						
IN India	[X]	[X]					[X]
IRE Ireland	[X]		[X]	[X]	[X]	[X]	[X]
IS Israel							[X]
J Japan		[X]					
KE Kenya	[X]	[X]			[X]		
KU Kuwait		[X]					
LEB Lebanon		[X]					
MA Malaysia		[X]		[X]			
MO Morrocco					[X]		
NE Netherlands			[X]				
NG Nigera			[X]				
NO Norway		[X]					
NZ New Zealand		[X]					[X]
OM Oman	[X]		[X]	[X]			[X]
P Poland					[X]	[X]	
PA Pakistan		[X]		[X]		[X]	
PH Philippines						[X]	
PO Portugal		[X]	[X]				
SA South Africa				[X]	[X]	[X]	
SAU Saudi Arabia		[X]		[X]	[X]		[X]
SI Singapore				[X]	[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:

still selling worldwide, but not in consistant numbers,
Isreal and philippines and new countries on the list

Comments on Risks with Sales to Countries:

no risks identified with selling to Isreal or philippines.

Returns Information

Stock Reference	Fault	2007	2008	2009	2010	2011	2012	2013
2510000	Audio transducer replaced						1	
2510000	Battery contacts tightened.	1						
2510000	Control knob spins					1	2	
2510000	Damaged during transit		1					
2510000	Dead						3	1
2510000	Dry joint				1			
2510000	Faulty patient cable				1			
2510000	Faulty patient cable replaced			4	2	5		1
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	2	1
2510000	PCB assembly replaced			2	1		1	1
2510000	Tested OK		3		6			
2510000	Uneconomical to repair, service exchange			1				
2520000	No Fault Return to Stock							

Comments on Returns:

returns are very Low,
been a very stable good quality product.

Comments on Risks with Returns and Potential Re-work:

most returns are swapped for new units due to cost measures,
no risks are identified with return units.

Design Changes / Product Changes

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

no design changes have taken place.

Comments on Risks with Design Changes:

not applicable

User Instructions

Showing Documents Filed in F 5 User Instructions

Document ID	Description	Date Added/Updated
12210	Microstim MkIII Instructions for Use / User Manual Danish Certif...	29/11/12
12209	Microstim MkIII Instructions for Use / User Manual Danish	29/11/12
12205	Microstim MkIII Instructions for Use / User Manual English	27/11/12
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:

Manual was translated in to Danish, and certified.

Comments on Risks User Instructions:

no risks identified with new 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:

not applicable

Documentation Updates / Changes

Comments on Document Changes:

only updated docuemtns are the canadian health updates and licences.

Comments on Risks with Document Changes:

no risks with the changed documentation.

Review of Issues

Number of Issues reviewed: 10

Issue ID	Subject
42694	Returned Items SOR564
40434	Returned Items SOR526
39641	Returned Items SOR509
37488	SOR526 - Queen Elizabeth Hospital
37558	FYI Microstim problems
37557	FYI Microstim problems
37556	FYI Microstim problems
38960	Peto / GHX spreadsheet corrections
37004	Modified Microstim
32901	Microstim - web site edits

Comments on Issues:

37558# users swapping to alternative supplier due to quality concerns,

further investigation lead to the way the users were wrapping the cables around the units and breaking the cables.

the Issue also note there should be a followup after a period of time to see if changing the way the store the units has made a difference to them breaking the cables.

Will further action this to ensure it has been done.

All other Issues are process / selling Issues.

Follow up Issue #43015

Comments on Risks with Issues:

no risks identified with the 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 :

Microstim`s are still wildly used.

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 reports were found.