



24/Mar/2011
Microstim MkIII

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Viamed Product
Post market Surveillance
Risk Assessment
Stock References Review
Supplier Review
Sales Review
Country Sales Review
Stock Returns Review
Design Changes Review
Document Updates Review
Internal Issues Review
Clinical Information Review
FDA Incidents Review
Carried out by Derek Lamb on 24 / 03 / 11

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:

All relevant stock references listed

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:

all suppliers rated

Sales Information

Stock Reference	Description	2005	2006	2007	2008	2009	2010	2011
2510000	Microstim DB3 - Supramaximal Nerve	1	58	205	450	377	194	47
2510001	Microstim DB3 - Supramaximal Nerve						49	
2520000	Microstim DB3 - Patient Lead.		3	19	135	167	253	68

Comments on Sales Information:

Units are still selling

New Countries

Country	2005	2006	2007	2008	2009	2010	2011
AUS Australia					[X]	[X]	
B Belgium				[X]		[X]	
CAN Canada				[X]	[X]	[X]	[X]
CY Cyprus							[X]
CZ Czech Republic				[X]			
DE Denmark				[X]			
EG Egypt					[X]		
FI Finland		[X]	[X]	[X]	[X]	[X]	[X]
G Germany		[X]					
GR Greece				[X]	[X]	[X]	
HK Hong Kong		[X]			[X]		
I Iran			[X]				
IN India	[X]	[X]	[X]	[X]			
IRE Ireland		[X]	[X]		[X]	[X]	[X]
J Japan				[X]			
KE Kenya			[X]	[X]			
KU Kuwait				[X]			
LEB Lebanon				[X]			
MA Malaysia				[X]		[X]	
NE Netherlands					[X]		
NG Nigera					[X]		
NO Norway				[X]			
NZ New Zealand				[X]			
OM Oman			[X]		[X]	[X]	
PA Pakistan				[X]		[X]	
PO Portugal				[X]	[X]		
SA South Africa						[X]	[X]
SAU Saudi Arabia				[X]		[X]	[X]
SI Singapore						[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]

Comments on Sales to Countries:

Units still being sold internationally

Comments on Risks with Sales to Countries:

Cyprus is the only new country, no risks identified with selling units to cyprus

Returns Information

Stock Reference	Fault	2005	2006	2007	2008	2009	2010	2011
2510000	Battery contacts tightened.			1				
2510000	Damaged during transit				1			
2510000	Dry joint						1	
2510000	Faulty patient cable						1	
2510000	Faulty patient cable replaced					4	2	
2510000	Intensity knob fitted					1	2	
2510000	Investigate						1	
2510000	Leads replaced			1			2	1
2510000	LED replaced				1			
2510000	Modified to PN:2510001						39	
2510000	No output				2	1	3	
2510000	PCB assembly replaced					2	1	
2510000	Tested OK				3		6	
2510000	Uneconomical to repair, service exchange					1		
2520000	No Fault Return to Stock							

Comments on Returns:

Limited number of returns,less than 2% failure rate

Comments on Risks with Returns and Potential Re-work:

no risks identified with returns and or reworks

Design Changes / Product Changes

Showing Documents Filed in Y 14 Design Changes

Document ID	Added on	Added By	Description
8098	18/03/11	John Lamb	Microstim Design Changes Q28 Microstim Design Changes Q28
8090	18/03/11	John Lamb	Microstim Design Changes DB2 Capacitor movement

Comments on Design Changes:

Minor capacitor change

Comments on Risks with Design Changes:

No risk identified with Capacitor change

Documentation updates / Changes

Document ID	Added on	Added By	Description
8119	22/03/11	Derek Lamb	Microstim MkIII Test Reports 2009 batch test
8117	22/03/11	John Lamb	CE FILE Microstim MkIII EC Declaration of Conformance DB3
8107	21/03/11	John Lamb	Microstim MkIII Clinical Trials
8081	17/03/11	John Lamb	CE FILE Microstim MkIII Design Compliance Design Compliance_Microstim
8069	17/03/11	John Lamb	CE FILE Microstim Specifications of Materials DB60
8056	17/03/11	John Lamb	Microstim MkIII Test Reports
8055	17/03/11	John Lamb	CE FILE Microstim MkIII Software 27_01_1991
8054	17/03/11	John Lamb	Microstim MkIII Test Reports
8052	17/03/11	John Lamb	Microstim MkIII Design Reviews QC24 case review 2005 May
8049	17/03/11	John Lamb	Microstim MkIII Design Reviews QC24 2005 May
8048	17/03/11	John Lamb	Microstim MkIII Design Reviews QC24 Tx output voltage
8045	17/03/11	John Lamb	Microstim MkIII OES (OEM) CE Certificate
8043	16/03/11	John Lamb	Machinery Directive Not Applicable
8035	16/03/11	Derek Lamb	CE FILE Microstim Pre-Clinical Trials Data
8034	16/03/11	Derek Lamb	Microstim MkIII Risk management review Yearly Report

Comments on Document Changes:

Various document updated due to March 2010 Regulation changes

Comments on Risks with Document Changes:

No risk identified with Document Changes

Review of Issues

Number of Issues reviewed: 72

Comments on Issues:

no comments on Issues

Comments on Risks with Issues:

No risks Identified with Issues

Review of online clinical reports

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

Do any of the Results indicate Microstim MkIII is outdated Technology Microstim MkIII : No

Comments on Clinical Search :

No relevant Clinical reports found,

Units still Current

Review of online FDA Incident reports

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

Do any of the Results indicate Microstim MkIII is outdated Technology Microstim MkIII : No

Comments on Clinical Search :

No relevant FDA incident reports found,
Units still Current