



23/May/2013

Post market Surveillance and Risk Assessment Re-evaluation

FlowSensors
Viamed OBL 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 23 / 05 / 13

Stock References Reviewed

Stock Reference	Description
4310001	Flowsensors - A. Pack of 5.
4310003	Flowsensors - H. Pack of 6.
4330001	Flowsensor - A.
4330003	Flowsensor - H.

Comments on Stock references review:

Part number correct

Supplier Information on Main and Component Parts

Stock Reference	Description	Supplier A/C	Supplier Name	Rating
4310001	Flowsensors - A. Pack of 5.	00009300	Bluepoint Medical	A
4310003	Flowsensors - H. Pack of 6.	00009300	Bluepoint Medical	A

Comments on Suppliers:

Single source supplier as products are own brand labeled

Sales Information

Stock Reference	Description	2007	2008	2009	2010	2011	2012	2013
4310001	Flowsensors - A. Pack of 5.			212	680	1166	1168	330
4310003	Flowsensors - H. Pack of 6.			2		259	276	107
4330001	Flowsensor - A.			6	8	3	6	
4330003	Flowsensor - H.			1	1	6	1	

Comments on Sales Information:

Units still selling. although numbers appear to be dropping in 2013

New Countries

Country	2007	2008	2009	2010	2011	2012	2013
AL Algeria					[X]		
AU Austria			[X]				
B Belgium					[X]		
EG Egypt					[X]	[X]	
ES Estonia					[X]		
G Germany			[X]				
GEO Georgia					[X]		
GR Greece				[X]	[X]	[X]	[X]
IN India			[X]	[X]			
JO Jordan					[X]	[X]	
MA Malaysia			[X]				
MO Morrocco					[X]	[X]	[X]
NO Norway				[X]			
P Poland						[X]	
PA Pakistan					[X]		
RO Romania						[X]	[X]
SAU Saudi Arabia				[X]	[X]		
SER Serbia					[X]		
SP Spain					[X]	[X]	[X]
SRI Sri Lanka							[X]
T Turkey			[X]	[X]	[X]	[X]	[X]
UK United Kingdom			[X]	[X]	[X]	[X]	[X]
VI Vietnam						[X]	

Comments on Sales to Countries:

We dont seem to keep supplying countrys after first batch of sales, might need looking into.
Follow up Issue #42993

Comments on Risks with Sales to Countries:

poland, romania and sri lanka and Vietnam are new countrys,
No risks identified with the new countries

Returns Information

Stock Reference	Fault	2007	2008	2009	2010	2011	2012	2013
4310001	No Fault Return to Stock							
4330001	Failed calibration			1				
4330001	Investigated						1	
4330001	No Fault Found						2	

Comments on Returns:

no returns

Comments on Risks with Returns and Potential Re-work:

no applicable

Design Changes / Product Changes

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

no new documentation

Comments on Risks with Design Changes:

not applicable

User Instructions

Showing Documents Filed in F 5 User Instructions

Document ID	Description	Date Added/Updated
7696	SpiroTrue / Flowsensor H Flowsensor user instructions	17/02/11
7124	SpiroTrue / Flowsensor A Flowsensor User Instruction	17/06/10

Comments on User Instructions:

no user instruction updates

Comments on Risks User Instructions:

not applicable

Labels

Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
7084	FlowSensors Labels flowsensorH	18/05/10
6586	FlowSensors Labels IMAG0103 Packet label	08/10/09
6585	FlowSensors Labels IMAG0102 Box label	08/10/09

Comments on Labels:

Comments on Risks Labels:

not applicable

Documentation Updates / Changes

Comments on Document Changes:

only new documents are photo of sampling line, and last years pms

Comments on Risks with Document Changes:

not applicable

Review of Issues

Number of Issues reviewed: 8

Issue ID	Subject
33816	CCn 143 Flowsensor A`s
34189	Flowsensor reserve stock
38240	Export Links
38432	Flowsensor A Sales
38431	Flowsensor A Sales
41952	Flowsensors - USD Distributor Price List
39536	4310003 Hamilton flow sensor - customer feedback
32905	Flow Sensors - web site update

Comments on Issues:

1 Issue on the question of reliability, which seems to have been solved, (#38431)

otherwise no problems identified in the issues system

Comments on Risks with Issues:

no risks identified

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 :

Compatible product to existing OEM,
OEM product still relevant

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 have been found