



16/May/2012

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 16 / 05 / 12

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:

No new partnumbers

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:

Supplier review is uptodate

Sales Information

Stock Reference	Description	2006	2007	2008	2009	2010	2011	2012
4310001	Flowsensors - A. Pack of 5.				212	680	1166	387
4310003	Flowsensors - H. Pack of 6.				2		259	82
4330001	Flowsensor - A.				6	8	3	1
4330003	Flowsensor - H.				1	1	6	

Comments on Sales Information:

sales appear slightly down on 2011

New Countries

Country	2006	2007	2008	2009	2010	2011	2012
AL Algeria						[X]	
AU Austria				[X]			
B Belgium						[X]	
EG Egypt						[X]	
ES Estonia						[X]	
G Germany				[X]			
GEO Georgia						[X]	
GR Greece					[X]	[X]	[X]
IN India				[X]	[X]		
JO Jordan						[X]	[X]
MA Malaysia				[X]			
MO Morrocco						[X]	
NO Norway					[X]		
PA Pakistan						[X]	
SAU Saudi Arabia					[X]	[X]	
SER Serbia						[X]	
SP Spain						[X]	[X]
T Turkey				[X]	[X]	[X]	[X]
UK United Kingdom				[X]	[X]	[X]	[X]

Comments on Sales to Countries:

New countries , AL Algeria , B Belgium , EG Egypt , ES Estonia , GEO Georgia , MO Morrocco , PA Pakistan , SER Serbia all recieved samples / purchased in 2011 but have not bought any in 2012, no indication at this point as to why.
Follow up Issue #36554

Comments on Risks with Sales to Countries:

No risks identified with selling to new countries

Returns Information

Stock Reference	Fault	2006	2007	2008	2009	2010	2011	2012
4310001	No Fault Return to Stock							
4330001	Failed calibration				1			
4330001	Investigated							1
4330001	No Fault Found							2

Comments on Returns:

low returns

Comments on Risks with Returns and Potential Re-work:

returns - returned to supplier therefore no risk associated with returns / reworks

Design Changes / Product Changes

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

No documents in Design Changes

Comments on Risks with Design Changes:

no risks

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:

User Instructions have been updated / PDF

Comments on Risks User Instructions:

no risks identified with instructions

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:

no risks associated with labels

Documentation Updates / Changes

Comments on Document Changes:

technical files updated to include requirements of new essencial requirements

Comments on Risks with Document Changes:

No risks identified with new documentation

Review of Issues

Number of Issues reviewed: 12

Issue ID	Subject
29774	Request Scanning Item to Sale or return
34188	Discrepancy between Opera and Intrastats
33816	CCN 143 Flowsensor A`s
29409	4310001 true stock figure
29408	4310001 true stock figure
29407	4310001 true stock figure
29406	4310001 true stock figure
33207	Urgent QA issue - Bag sealing problem, flowsensor H
33206	Urgent QA issue - Bag sealing problem, flowsensor H
34189	Flowsensor reserve stock
32905	Flow Sensors - web site update
29142	Additional Flowsensor A Customer

Comments on Issues:

CCN 143, Users appears to have used a substance to clean a flowsensor, which in turn caused it to burn. See issue 33816, On going investigation with MHRA. last contact we believe its being put down to user error, and the user instructions contains enough warnings to alert the user of the associated risks of incorrect cleaning.

Comments on Risks with Issues:

CCN 143 Issue 33816. No further action at this time required

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 :

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 :