



24/May/2013

Post market Surveillance and Risk Assessment Re-evaluation

Nova Oxygen Tents
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 24 / 05 / 13

Stock References Reviewed

Stock Reference	Description
2310000	Oxygen hood/tent - standard.
2310001	Oxygen hood/tent - standard.
2310002	Oxygen hood/tent - standard.
2310003	Oxygen hood/tent - standard.
2310004	Oxygen hood/tent - standard.
2310005	Oxygen hood/tent - standard.
2310006	Oxygen hood/tent - standard.
2310007	Oxygen hood/tent - standard.
2310008	Oxygen hood/tent - standard.
2310009	Oxygen hood/tent - standard.
2310010	Oxygen hood/tent - standard.
2310011	Oxygen hood/tent - standard.
2310012	Oxygen hood/tent - standard.
2310013	Oxygen hood/tent - standard.
2310014	Oxygen hood/tent - standard.
2310020	Oxygen hood/tent - dual port.
2310021	Oxygen hood/tent - ICN with 3 ports.
2310025	Oxygen hood/tent - no bottom.
2310026	Oxygen hood/tent - no bottom.
2310027	Oxygen hood/tent - no bottom.
2310028	Oxygen hood/tent - no bottom.
2310029	Oxygen hood/tent - no bottom.
2310030	Oxygen hood/tent - no bottom.
2310031	Oxygen hood/tent - no bottom.
2310032	Oxygen hood/tent - no bottom.
2310033	Oxygen hood/tent - no bottom.
2310034	Oxygen hood/tent - no bottom.
2310035	Oxygen hood/tent - no bottom.
2310050	Oxygen hood/tent - partial bottom.
2310051	Oxygen hood/tent - partial bottom.
2310052	Oxygen hood/tent - partial bottom.
2310053	Oxygen hood/tent - partial bottom.
2310054	Oxygen hood/tent - partial bottom.
2310055	Oxygen hood/tent - partial bottom.
2310075	Oxygen hood/tent - NICU.
2310076	Oxygen hood/tent - NICU.
2310077	Oxygen hood/tent - NICU.
2310078	Oxygen hood/tent - NICU.
2310079	Oxygen hood/tent - NICU.
2310080	Oxygen hood/tent - NICU.
2310081	Oxygen hood/tent - NICU.
2310100	Low birth weight tenthouse
2310101	Low birth weight tenthouse w/port
2310102	Low birth weight tenthouse top access
2310103	Low birth weight tenthouse with top &

Stock Reference	Description
2310104	Low birth weight tenthouse
2310105	Low birt weight tenthouse w/port.
2310106	Low birth weight tenthouse top access
2310107	Low birth weight tenthouse with top &
2310125	Double tent set
2310126	Double tent set
2310127	Double tent set
2310128	Double tent set inner no bottom
2310129	Double tent set
2310130	Double tent set
2310131	Double tent - outer tent only for use
2310132	Double tent - outer tent only for use
2310133	Double tent - outer tent only for use
2310134	Double tent - outer tent only for use
2310140	Babyshield - infant heat shield
2310141	Babyshield - infant heat shield with
2310145	Oxygen hood - no drape.
2310150	Isolation canopy - chair.
2310151	Isolation canopy - crib.
2330000	Oxygen hood/tent - standard.
2330001	Oxygen hood/tent - standard.
2330002	Oxygen hood/tent - standard.
2330003	Oxygen hood/tent - standard.
2330004	Oxygen hood/tent - standard.
2330006	Oxygen hood/tent - standard.
2330007	Oxygen hood/tent - standard.
2330010	Oxygen hood/tent - standard.
2330011	Oxygen hood/tent - standard.
2330013	Oxygen hood/tent - standard.
2330014	Oxygen hood/tent - standard.
2330020	Oxygen hood/tent - dual port.
2330021	Oxygen hood/tent - ICN with 3 ports.
2330025	Oxygen hood/tent - no bottom.
2330026	Oxygen hood/tent - no bottom.
2330027	Oxygen hood/tent - no bottom.
2330028	Oxygen hood/tent - no bottom.
2330029	Oxygen hood/tent - no bottom.
2330031	Oxygen hood/tent - no bottom.
2330032	Oxygen hood/tent - no bottom.
2330035	Oxygen hood/tent - no bottom.
2330050	Oxygen hood/tent - partial bottom.
2330052	Oxygen hood/tent - partial bottom.
2330053	Oxygen hood/tent - partial bottom.
2330055	Oxygen hood/tent - partial bottom.
2330075	Oxygen hood/tent - NICU.
2330076	Oxygen hood/tent - NICU.
2330077	Oxygen hood/tent - NICU.
2330078	Oxygen hood/tent - NICU.
2330080	Oxygen hood/tent - NICU.

Stock Reference	Description
2330081	Oxygen hood/tent - NICU.

Comments on Stock references review:

Supplier Information on Main and Component Parts

Stock Reference	Description	Supplier A/C	Supplier Name	Rating
2310000	Oxygen hood/tent - standard.	00012241	Nova Health Systems	b
2310001	Oxygen hood/tent - standard.	00012241	Nova Health Systems	b
2310002	Oxygen hood/tent - standard.	00012241	Nova Health Systems	b
2310003	Oxygen hood/tent - standard.	00012241	Nova Health Systems	b
2310004	Oxygen hood/tent - standard.	00012241	Nova Health Systems	b
2310006	Oxygen hood/tent - standard.	00012241	Nova Health Systems	b
2310007	Oxygen hood/tent - standard.	00012241	Nova Health Systems	b
2310010	Oxygen hood/tent - standard.	00012241	Nova Health Systems	b
2310011	Oxygen hood/tent - standard.	00012241	Nova Health Systems	b
2310013	Oxygen hood/tent - standard.	00012241	Nova Health Systems	b
2310014	Oxygen hood/tent - standard.	00012241	Nova Health Systems	b
2310020	Oxygen hood/tent - dual port.	00012241	Nova Health Systems	b
2310021	Oxygen hood/tent - ICN with 3 ports.	00012241	Nova Health Systems	b
2310025	Oxygen hood/tent - no bottom.	00012241	Nova Health Systems	b
2310026	Oxygen hood/tent - no bottom.	00012241	Nova Health Systems	b
2310027	Oxygen hood/tent - no bottom.	00012241	Nova Health Systems	b
2310028	Oxygen hood/tent - no bottom.	00012241	Nova Health Systems	b
2310029	Oxygen hood/tent - no bottom.	00012241	Nova Health Systems	b
2310031	Oxygen hood/tent - no bottom.	00012241	Nova Health Systems	b
2310032	Oxygen hood/tent - no bottom.	00012241	Nova Health Systems	b
2310035	Oxygen hood/tent - no bottom.	00012241	Nova Health Systems	b
2310050	Oxygen hood/tent - partial bottom.	00012241	Nova Health Systems	b
2310052	Oxygen hood/tent - partial bottom.	00012241	Nova Health Systems	b
2310055	Oxygen hood/tent - partial bottom.	00012241	Nova Health Systems	b
2310075	Oxygen hood/tent - NICU.	00012241	Nova Health Systems	b
2310076	Oxygen hood/tent - NICU.	00012241	Nova Health Systems	b
2310077	Oxygen hood/tent - NICU.	00012241	Nova Health Systems	b
2310078	Oxygen hood/tent - NICU.	00012241	Nova Health Systems	b
2310080	Oxygen hood/tent - NICU.	00012241	Nova Health Systems	b
2310081	Oxygen hood/tent - NICU.	00012241	Nova Health Systems	b
2310100	Low birth weight tenthouse	00012241	Nova Health Systems	b
2310104	Low birth weight tenthouse	00012241	Nova Health Systems	b
2310107	Low birth weight tenthouse with top &	00012241	Nova Health Systems	b
2310125	Double tent set	00012241	Nova Health Systems	b
2310140	Babyshield - infant heat shield	00012241	Nova Health Systems	b
2310141	Babyshield - infant heat shield with	00012241	Nova Health Systems	b

Comments on Suppliers:

Part numbers checked and verified

Sales Information

Stock Reference	Description	2007	2008	2009	2010	2011	2012	2013
2310000	Oxygen hood/tent - standard.		9		2	3	-3	
2310001	Oxygen hood/tent - standard.	1	4	2	7		5	1
2310002	Oxygen hood/tent - standard.	1			6	2		
2310003	Oxygen hood/tent - standard.						1	2
2310004	Oxygen hood/tent - standard.	5	6	1	12		2	
2310005	Oxygen hood/tent - standard.							
2310006	Oxygen hood/tent - standard.		5	6	11	18	2	2
2310007	Oxygen hood/tent - standard.	28	15	21	39	31	25	4
2310008	Oxygen hood/tent - standard.							
2310009	Oxygen hood/tent - standard.							
2310010	Oxygen hood/tent - standard.	23	30	59	57	47	60	14
2310011	Oxygen hood/tent - standard.	9	2	2				
2310012	Oxygen hood/tent - standard.							
2310013	Oxygen hood/tent - standard.	10	13	21	34	29	28	11
2310014	Oxygen hood/tent - standard.	3	3		4	6		
2310020	Oxygen hood/tent - dual port.							
2310021	Oxygen hood/tent - ICN with 3 ports.							
2310025	Oxygen hood/tent - no bottom.							
2310026	Oxygen hood/tent - no bottom.							
2310027	Oxygen hood/tent - no bottom.							
2310028	Oxygen hood/tent - no bottom.							
2310029	Oxygen hood/tent - no bottom.					10		
2310030	Oxygen hood/tent - no bottom.							
2310031	Oxygen hood/tent - no bottom.					5	4	
2310032	Oxygen hood/tent - no bottom.			1	1	18	21	4
2310033	Oxygen hood/tent - no bottom.							
2310034	Oxygen hood/tent - no bottom.							
2310035	Oxygen hood/tent - no bottom.			2	7	29	33	7
2310050	Oxygen hood/tent - partial bottom.							
2310051	Oxygen hood/tent - partial bottom.							
2310052	Oxygen hood/tent - partial bottom.						4	
2310053	Oxygen hood/tent - partial bottom.							
2310054	Oxygen hood/tent - partial bottom.							
2310055	Oxygen hood/tent - partial bottom.							2
2310075	Oxygen hood/tent - NICU.							
2310076	Oxygen hood/tent - NICU.				2			
2310077	Oxygen hood/tent - NICU.							
2310078	Oxygen hood/tent - NICU.				2			
2310079	Oxygen hood/tent - NICU.							
2310080	Oxygen hood/tent - NICU.							
2310081	Oxygen hood/tent - NICU.				2			
2310100	Low birth weight tenthouse							
2310101	Low birth weight tenthouse w/port							
2310102	Low birth weight tenthouse top access							
2310103	Low birth weight tenthouse with top &							
2310104	Low birth weight tenthouse							

Stock Reference	Description	2007	2008	2009	2010	2011	2012	2013
2310105	Low birt weight tenthouse w/port.							
2310106	Low birth weight tenthouse top access							
2310107	Low birth weight tenthouse with top &							
2310125	Double tent set							
2310126	Double tent set							
2310127	Double tent set							
2310128	Double tent set inner no bottom							
2310129	Double tent set							
2310130	Double tent set							
2310131	Double tent - outer tent only for use							
2310132	Double tent - outer tent only for use							
2310133	Double tent - outer tent only for use							
2310134	Double tent - outer tent only for use							
2310140	Babyshield - infant heat shield							
2310141	Babyshield - infant heat shield with							
2310145	Oxygen hood - no drape.							
2310150	Isolation canopy - chair.							
2310151	Isolation canopy - crib.							
2330000	Oxygen hood/tent - standard.		2	2		1		
2330001	Oxygen hood/tent - standard.		1	2	1	1		
2330002	Oxygen hood/tent - standard.		1			2		
2330003	Oxygen hood/tent - standard.							
2330004	Oxygen hood/tent - standard.			2				
2330006	Oxygen hood/tent - standard.		1	1				
2330007	Oxygen hood/tent - standard.		1	3				
2330010	Oxygen hood/tent - standard.		1					
2330011	Oxygen hood/tent - standard.							
2330013	Oxygen hood/tent - standard.	1	1	1				
2330014	Oxygen hood/tent - standard.						1	
2330020	Oxygen hood/tent - dual port.							
2330021	Oxygen hood/tent - ICN with 3 ports.							
2330025	Oxygen hood/tent - no bottom.							
2330026	Oxygen hood/tent - no bottom.							
2330027	Oxygen hood/tent - no bottom.							
2330028	Oxygen hood/tent - no bottom.							
2330029	Oxygen hood/tent - no bottom.							
2330031	Oxygen hood/tent - no bottom.						1	
2330032	Oxygen hood/tent - no bottom.							
2330035	Oxygen hood/tent - no bottom.						4	
2330050	Oxygen hood/tent - partial bottom.							
2330052	Oxygen hood/tent - partial bottom.							
2330053	Oxygen hood/tent - partial bottom.							
2330055	Oxygen hood/tent - partial bottom.							
2330075	Oxygen hood/tent - NICU.				1	1		
2330076	Oxygen hood/tent - NICU.							
2330077	Oxygen hood/tent - NICU.							
2330078	Oxygen hood/tent - NICU.							
2330080	Oxygen hood/tent - NICU.							
2330081	Oxygen hood/tent - NICU.							

Comments on Sales Information:

units still selling, however sales do appear to be down.

New Countries

Country	2007	2008	2009	2010	2011	2012	2013
B Belgium			[X]	[X]			
F France							
G Germany		[X]					
GR Greece				[X]			
IRE Ireland				[X]	[X]	[X]	
JO Jordan							
NE Netherlands				[X]	[X]		
P Poland			[X]		[X]	[X]	
SP Spain		[X]	[X]				
SW Sweden					[X]		
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	[X]

Comments on Sales to Countries:

no NEW countries have been buying

Comments on Risks with Sales to Countries:

no risks identified with countries purchasing

Returns Information

Comments on Returns:

Zero returns,

Comments on Risks with Returns and Potential Re-work:

not applicable

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
8969	Nova Oxygen Tents Instructions for Use / User Manual	18/10/11

Comments on User Instructions:

no changes to the user manual

Comments on Risks User Instructions:

not applicable

Labels

Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
8961	Nova Oxygen Tents Accessory Labels List of Accessories	18/10/11
7690	Nova Oxygen Tents Labels	15/02/11

Comments on Labels:

Comments on Risks Labels:

not applicable

Documentation Updates / Changes

Comments on Document Changes:

no new documents have been added to the system

Comments on Risks with Document Changes:

not applicable

Review of Issues

Number of Issues reviewed: 2

Issue ID	Subject
30332	Returned Items SOR478
40331	Alternative products

Comments on Issues:

Issues are selling issues, no problems found

Comments on Risks with Issues:

no risk found in the issues system

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 :

nothing found searching google.

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