Ikaria INOmax DS Drug Delivery System: Class I Recall - Erratic Nitric Oxide (NO) Readings

U.S. Food & Drug Administration

AUDIENCE: Pulmonology, Risk Manager

ISSUE: FDA notified healthcare professionals of a Class I recall of Ikaria INOmax DS Drug Delivery System. Erratic nitric oxide (NO) monitoring readings were being caused by fretting corrosion at the electrical contact interface of certain metals. Adverse consequences may include inadequate oxygen reaching the tissues in the body (hypoxia), low blood pressure (hypotension), slower than normal heart rate (bradycardia), cardiac arrest, organ damage, acute respiratory distress syndrome (ARDS), neurological deficits, or death.

Affected serial numbers include DS20070005-DS20100865. This product was manufactured from March 12, 2007 through February 2, 2011 and distributed from September 4, 2007 through February 2, 2011.

BACKGROUND: INOmax DS Delivery System is a drug delivery system used with ventilators to deliver a preset concentration of INOmax therapy gas (nitric oxide for inhalation) for critically ill patients.

RECOMMENDATION: Ikaria implemented a service process change involving the application of DeoxIT, an anti-corrosion lubricant specifically created to prevent fretting corrosion. DeoxIT was added to the preventive maintenance plan for all INOmax DS Drug Delivery Systems and was performed when the Systems rotated through Ikaria’s Regional Service Centers for any routine service activity.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm [1]
- Download form [2] or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[01/04/2011 - Recall Notice [3] - FDA]

Related MedWatch Alert:

[08/23/2010 [4]]

SOURCE [5]

Source URL (retrieved on *11/28/2014 - 8:14am*):
http://www.mdtmag.com/news/2012/01/ikaria-inomax-ds-drug-delivery-system-class-i-recall-erratic-nitric-oxide-no-readings

Links:
[1] http://www.fda.gov/MedWatch/report.htm
[2] http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
[3] http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm285725.htm
[4] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm223746.htm
[5] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm285803.htm