FDA Home³ Medical Devices⁴ Databases⁵

Class 2 Device Recall Fresenius Medical Naturalyte Liquid Bicarbonate Concentrate
510(k)⁷|DeNovo⁸|Registration & Listing⁹|Adverse Events¹⁰|Recalls¹¹|PMA¹²|Classification¹³|Standards¹⁴

() CEN

CFR Title | Radiation-Emitting 21¹⁵ Products¹⁶

tting | X-Ray

Medsun

|CLIA¹⁹|TPLC²⁰|Inspections²¹

Products¹⁶ Assembler¹⁷ Reports¹⁸

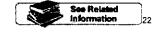
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Class 2 Recall
Fresenius Medical Natura

Fresenius Medical Naturalyte Liquid

Bicarbonate Concentrate



Date Posted

September 23, 2014

Recall Status¹

Open

Recall Number

Z-2686-2014

Recall Event ID

69158²³

Premarket Notification

K071387²⁴

510(K) Number

Product Classification

<u>Dialysate Concentrate For Hemodialysis (Liquid Or Powder)</u>²⁵ - **Product Code** <u>KPO</u>²⁶

Product

Fresenius Naturalyte Liquid Bicarbonate Concentrate Product Number: 08-4000-LB The concentrate is formulated to be used with a three steam hemodialysis machine

which is calibrated for acid and bicarbonate concentrates.

Code Information

Lot Number: 14BMLB012

Recalling Firm/ Manufacturer Fresenius Medical Care Holdings, Inc.

920 Winter St

Waltham, Massachusetts 02451-1521

For Additional Information Contact

Same

800-662-1237

Manufacturer Reason for Recall

Product was held at temperature above the labeled recommended storage temperature

FDA Determined Cause ²

PRODUCTION CONTROLS: Storage

Action

Fresenius Medical North America contacted customers via telephone on 6/23/14 by Customer Service and follow-up with formal letter notification, Urgent Recall by certified mail with signature confirmation and faxback form Customers instructed to examine their inventory to determine whether they have any of the affected Naturalyte Liquid Bicarbonate. If customers have the affected product, they are instructed to contact FMC-RTG Customer Service to have the product replaced. A revised/clarification letter dated 7/10/14 issued to state only products from the identified lots that were delivered by RTG LLC to the specified facilities on May 5, 2014 are affected by this recell or products were expected to

facilities on May 5, 2014 are affected by this recall as products were exposed to temperatures higher than their recommended storage temperature during transportation on May 5, 2014. If you have any additional questions, please contact your FMCNA Customer

Service Team at 1-800-323-5188.

Quantity in Commerce

72 cases

Distribution

Distributed in Texas.

Total Product Life Cycle

TPLC Device Report²⁷

¹ For details about termination of a recall see <u>Code of Federal Regulations (CFR) Title 21 §7.55²⁸</u>

² Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.