Class 1 Recall
Naturalyte Liquid Bicarbonate Concentrate

Date Posted: May 22, 2014
Recall Status: Open
Recall Number: Z-1639-2014
Recall Event ID: 67922
Premarket Notification 510(K) Number: K071387

Product Classification: Dialysate Concentrate For Hemodialysis (Liquid Or Powder) - Product Code KPO

Product: Naturalyte Liquid Bicarbonate Concentrate, 6.4 Liter Bottle Part Number: 08-4000-LB
The concentrate is formulated to be used with a three stream hemodialysis machine which is calibrated for acid and bicarbonate concentrates.

Code Information: Lot Numbers (49 lots) recalled on 4/10/14: 13KMLB001 13MLMLB001 14AMLB002 13KMLB002 13MLMLB002 14AMLB003 13KMLB003 13MLMLB003 14AMLB004 13KMLB004 14AMLB005 13KMLB005 13MLMLB005 14AMLB006 13KMLB006 13MLMLB006 14AMLB007 13KMLB007 13MLMLB007 14AMLB008 13KMLB008 13MLMLB008 14AMLB009 13KMLB009 13MLMLB009 14AMLB010 13KMLB010 13MLMLB010 14AMLB011 13KMLB011 13MLMLB011 14AMLB012 13KMLB012 13MLMLB012 14AMLB013 13KMLB013 13MLMLB013 14AMLB014 13KMLB014 13MLMLB014 14AMLB015 13KMLB015 13MLMLB015 14AMLB016 13KMLB016 13MLMLB016 14AMLB017 13KMLB017 14AMLB017

Recalling Firm/Manufacturer: Fresenius Medical Care Holdings, Inc.
920 Winter St
Waltham, Massachusetts 02451-1521

Manufacturer Reason for Recall: Naturalyte Liquid Bicarbonate may be contaminated

FDA Determined Cause: OTHER/UNDETERMINED: Under investigation by the firm

Action: Fresenius Medical Care North America issued an Urgent Medical Device Recall Letter dated April 10, 2014, to all affected customers. The letter identified the product, the problem, and the action to be taken by the customer. Customers were instructed to examine their stock immediately and determine whether they have any of the affected parts on hand. If customers have the affected product, they were instructed to discontinue use and place all Naturalyte Liquid Bicarbonate Concentrate in a secure area for return to Fresenius Medical Care Renal Therapies Group, LLC (FMC-RTG). Customers will be instructed to contact their Fresenius Medical Care Technical Service Team for instructions on how to return the recalled product. Firm will also conduct 100% telephone calls. If you have any additional questions, please contact your FMCNA Customer Service Team at 1-800-323-5188. Fresenius Medical Care issued an Urgent Expanded Medical Device Recall letter on May 1, 2014 for 9 additional lots. Customers were instructed to complete and return the attached FAX BACK FORM to confirm that they have received the notice and to indicate whether or not they have the affected product in their possession. For questions regarding this recall call 800-662-1237. Firm issued Press on 5/21/14.

Quantity in Commerce: 672,864 units

Distribution
Worldwide Distribution - USA (nationwide) and Canada.

Total Product Life Cycle
TPLC Device Report

1 For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 87.55
2 Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database
510(K)s with Product Code = KPC and Original Applicant = FRESENIUS MEDICAL CARE NORTH AMERICA

Links on this page:
4. http://www.fda.gov/MedicalDevices/default.htm
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20. /scripts/cdrh/cfdocs/cfTPLC/tplt.cfm
22. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=67922
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U.S. Food and Drug Administration
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