Class 2 Recall
Fresenius Medical Naturalyte Liquid Bicarbonate Concentrate

See Related Information[22]

Date Posted	September 23, 2014
Recall Status[1]	Open
Recall Number	Z-2686-2014
Recall Event ID	69158[23]
Premarket Notification 510(K) Number	K071387[24]
Product Classification	Dialysate Concentrate For Hemodialysis (Liquid Or Powder)[25] - **Product Code** KPO[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 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 Report[27]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[28]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.