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Class 2 Device Recall NaturaLyte Liquid Acid Concentrate

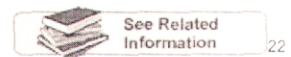


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Class 2 Device Recall NaturaLyte Liquid Acid Concentrate



Date Initiated by Firm	May 02, 2018
Create Date	June 07, 2018
Recall Status¹	Open ³ , Classified
Recall Number	Z-2110-2018
Recall Event ID	80101 ²³
510(K)Number	K070177 ²⁴
Product Classification	Dialysate concentrate for hemodialysis (liquid or powder) ²⁵ - Product Code KPO ²⁶
Product	NaturaLyte ² Liquid Acid Concentrate for Bicarbonate Dialysis, 3.43 Liters, Part Number: 08-3231-1 Product Usage: This concentrate is formulated to be used in conjunction with Fresenius Renal Technologies Sodium Bicarbonate Concentrate in a compatible 45X dilution three-stream artificial kidney (hemodialysis) machine. For every 45 volume parts of dialysate: 1 volume part of the NaturaLyte acid concentrate, 1.72 volume parts of FMCNA Sodium Bicarbonate Concentrate and 42.28 volume parts of Purified Water (AAMI quality) are used.
Code Information	Lot Code: 18CXAC095
Recalling Firm/Manufacturer	Fresenius Medical Care Renal Therapies Group, LLC 920 Winter St Waltham MA 02451-1521
For Additional Information Contact	800-227-2572
Manufacturer Reason for Recall	The bottles are mislabeled with an incorrect part number.
FDA Determined Cause²	Employee error
Action	Phone calls and Urgent Medical Device Recall notification letters were issued on 5/2/18. Customers were instructed to do the following: Immediately examine your stock to determine whether you have any NaturaLyte Liquid Acid from the lot listed above. If any products of this lot is found, discontinue use immediately. Place all units in a secure, segregated area. Contact your FMCRTG, LLC Customer Service Team at 1-800-323-5188 for instructions on how to return the recalled product and arrange for replacement product. Promptly fill out and return the attached reply form.
Quantity in Commerce	1060 cases (4240 bottles)
Distribution	Worldwide Distribution - US Nationwide in the states: CA, IA, IL, IN, KS, MD, MI, MN, MS, NE, NJ, NV, OK, PA, SD, TX, and WI.
Total Product Life Cycle	TPLC Device Report ²⁷