Class 2 Device Recall NaturaLyte Liquid Acid Concentrate

Date Initiated by Firm: May 02, 2018
Create Date: June 07, 2018
Recall Status: Open
Recall Number: Z-2110-2018
Recall Event ID: 80101
510(K)Number: K070177

Product Classification: Dialysate concentrate for hemodialysis (liquid or powder) - Product Code KPC

Product: NaturaLyte 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 Cause: 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

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfrRES/res.cfm?id=164557
6/18/2018