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**Class 2 Device Recall Fresenius NaturaLyte**

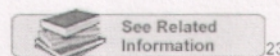


6 510(k) [DeNovo]<sup>7</sup> | Registration & Listing<sup>9</sup> | Adverse Events<sup>10</sup> | Recalls<sup>11</sup> | PMA<sup>12</sup> | HDE<sup>13</sup> | Classification<sup>14</sup> | Standards<sup>15</sup>  
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**Class 2 Recall  
Fresenius NaturaLyte**



<b>Date Posted</b>	June 22, 2015
<b>Recall Status<sup>1</sup></b>	Open
<b>Recall Number</b>	Z-1827-2015
<b>Recall Event ID</b>	<a href="#">71160<sup>24</sup></a>
<b>Premarket Notification 510(K) Number</b>	<a href="#">K071387<sup>25</sup></a>
<b>Product Classification</b>	<a href="#">Dialysate Concentrate For Hemodialysis (Liquid Or Powder)<sup>26</sup></a> - <b>Product Code</b> <a href="#">KPO<sup>27</sup></a>
<b>Product</b>	NaturaLyte Liquid Bicarbonate Concentrate (Dialysate Concentrate for Hemodialysis (liquid), 6.4 Liter Bottle Catalog Number: 08-4000-LB This concentrate is formulated to be used with a three steam hemodialysis machine which is calibrated for acid and bicarbonate concentrates.
<b>Code Information</b>	Affected lots begin with: 14DMLB, 14EMLB, 14HMLB, 14JMLB, 14KMLB, 14LMBL, 14NMLB, 14PMLB, and 14SMLB.
<b>Recalling Firm/Manufacturer</b>	Fresenius Medical Care Holdings, Inc. 920 Winter St Waltham, Massachusetts 02451-1521
<b>Manufacturer Reason for Recall</b>	Bacterial contamination.
<b>FDA Determined Cause<sup>2</sup></b>	PRODUCTION CONTROLS: Process Control
<b>Action</b>	Fresenius Medical Care sent an Urgent Medical Device Recall letter dated May 15, 2015, to all affected customers. Users were requested to Immediately examine stock to determine whether they have any NaturaLyte® Liquid Bicarbonate Concentrate of the lots. " If any product of these lots is found, discontinue use immediately. " Place all units in a secure, segregated area. " If affected product was on the machine prior to patient treatment, perform a [Heat Disinfect] program. " Your dialysis schedule should not be interrupted. If interruption of your dialysis schedule is expected, please discuss your options with your health care provider. " Contact FMCNA Customer Service Team at 1-800-323-5188 for instructions on how to return the recalled product. " Promptly fill out and return the attached reply form Additional medical concerns or questions, please contact Medical Information and Communication: 855-616-2309 or Website: <a href="http://www.fresenius-medinfo.com">www.fresenius-medinfo.com</a> . For questions regarding this recall call 800-662-1237.
<b>Quantity in Commerce</b>	1,856,619 Bottles
<b>Distribution</b>	Nationwide Distribution
<b>Total Product Life Cycle</b>	<a href="#">TPLC Device Report<sup>28</sup></a>

<sup>1</sup> For details about termination of a recall see [Code of Federal Regulations \(CFR\) Title 21 §7.55<sup>29</sup>](#)

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