

FDA Home³ Medical Devices⁴ Databases⁵

Class 2 Device Recall Lifeline Brand

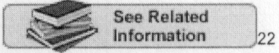


6 510(k)|DeNovo⁸ | Registration & Listing⁹ | Adverse Events¹⁰ | Recalls¹¹|PMA¹²|HDE¹³|Classification¹⁴|Standards¹⁵
 CFR Title 21¹⁶|Radiation-Emitting Products¹⁷|X-Ray Assembler¹⁸|Medsun Reports¹⁹|CLIA²⁰|TPLC²¹

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Class 2 Device Recall Lifeline Brand



Recall Date	July 06, 2016.
Recall Status¹	Open
Recall Number	Z-2132-2016
Recall Event ID	<u>74329</u> ²³
510(K)Number	<u>K083418</u> ²⁴
Product Classification	<u>Valve, non-rebreathing</u> ²⁵ - Product Code <u>CBP</u> ²⁶
Product	<p>Item # 4042-CPR Rescue Kit, containing CPR shield with one way valve & barrier filter. brand Lifeline, UPC 845174004429 each; UPC 845174004436 master case of 6.</p> <p>Item #4043-CPR Rescue Kit, containing CPR shield with one way valve & barrier filter. brand Lifeline.</p> <p>UPC Red color kit: 845174005464; UPC Lime color kit: 845174005594; UPC Purple color: 845174005600; UPC of master case of 6 845174005471 (2 each color)</p> <p>Item # 4037, Outfitter First Aid Kit, CPR shield with one way valve & barrier filter, brand Lifeline, UPC 845174003453</p>
Code Information	<p>item #4042 and item #4043 have the expiration date: 11/30/2017.</p> <p>Item #4037 has the following lots and expiration dates: Lot # Expiration Date 101483; 3/15 101546; 6/15 101682; 7/15 101804; 1/16 101812; 1/16 102032; 5/16 102109; 5/16 102098; 5/17 102130; 5/16 102296; 10/16 102317; 10/16 102295; 10/16 102372; 1/17 102638; 1/17 102694; 8/17</p>
Recalling Firm/Manufacturer	Lifeline First Aid LLC 26200 SW 95th Ave Ste 302 Wilsonville OR 97070-8204
For Additional Information Contact	Patti Douglas 503-783-3660