

FDA Home³ Medical Devices⁴ Databases⁵

Class 2 Device Recall General Motors brand

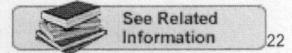


⁶ 510(k)|⁷ DeNovo⁸ | Registration & Listing⁹ | Adverse Events¹⁰ | Recalls¹¹|PMA¹²|HDE¹³|Classification¹⁴|Standards¹⁵
 CFR Title 21¹⁶|Radiation-Emitting Products¹⁷|X-Ray Assembler¹⁸|Medsun Reports¹⁹|CLIA²⁰|TPLC²¹

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Class 2 Device Recall General Motors brand



Recall Date	July 06, 2016
Recall Status¹	Open
Recall Number	Z-2133-2016
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	5195GM, Cadillac First Aid Kit, #23459698, brand General Motors. No UPC.
Code Information	Exp Dates/Lot # Jan-16; 14181 Nov-16; 15077 Nov-16; 15097 Mar-17; 15278 Oct-17; 16068
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
Manufacturer Reason for Recall	Cadillac First Aid Kit is recalled because it contains the CPR Shield with One Way Valve and Barrier Filter (mask) and this mask is cleared only for prescription use and is not cleared for over-the-counter (OTC) use.
FDA Determined Cause²	Other
Action	The firm sent the PRODUCT RECALL NOTICE- LIFELINE FIRST AID KITS WHICH INCLUDE CPR MASK letter, dated 5/11/2016, to their consignees. CPR shields will be replaced without charge and acceptable Lifeline First Aid kits will be re-worked and returned using our standard RGA process. In addition, the firm sent the PRODUCT RECALL NOTICE- CADILLAC FIRST AID KIT letter, dated May 31, 2016, to General Motors. General Motors will be sending out a dealership bulletin to inform their customers of this issue. Once confirmed, replacement masks will be sent to the requested dealerships and made available to be ordered (at no cost) as needed. Please complete and fax the attached Customer Response Form to Lifeline at (503)783-3721. Consignees with questions should call Lifeline First Aid, LLC at (503)783-3660.
Quantity in Commerce	2975 kits
Distribution	Distributed in AZ, CA, CO, FL, GA, IL, KY, MD, MN, MO, MT, NE, NJ, NY, OK, OR, PA, SC, TN, UT, VA, WA, WA, and WI. Also distributed in New Zealand.
Total Product Life Cycle	<u>TPLC Device Report</u> ²⁷