Class 2 Device Recall General Motors brand

Recall Date: July 06, 2016
Recall Status: Open
Recall Number: Z-2133-2016
Recall Event ID: 7432923
510(K) Number: K08341824
Product Classification: Valve, non-rebreathing - Product Code CBP
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
- 28200 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 Cause: 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: TPLC Device Report