Class 1 Device Recall Ventlab Manual Resuscitators

Class 1 Recall
Ventlab Manual Resuscitators

See Related Information[21]

Date Posted	July 03, 2014
Recall Status[1]	Open
Recall Number	Z-1948-2014
Recall Event ID	68242[22]
Premarket Notification 510(K) Numbers	K012842[23] K953546[24] K982215[25]
Product Classification	Ventilator, Emergency, Manual (Resuscitator)[26] - **Product Code** BTM[27]
Product	Manual Resuscitator Bag Series: AF1000, AF2000, AF3000, AF4000, AF5000, BT2000, BT3000, BT4000, BT5000, BVM700, CPRM1000, CPRM2000, CPRM3000, PRO-1900, PRO-1000, PRO-2000, SC7000, SC8000, SC8020, SC8120, SC9000, SS3200, VN2000, VN3000, VN4000, VN5000, VT1000 , VN2102, VN2002. Emergency manual resuscitator for the Pediatric Population.
Code Information	Manual Resuscitator Bag Series: AF1000, AF2000, AF5000, BT4000, VN2000, VN5000, VT1000; Lot #s105147 -107609. AF1000, AF2000, AF3000, AF4000, AF5000, BT2000, BT3000, BT4000, PRO-1900, SC7000, SC8120, SS3200, VN2000, VN3000, VN4000, VN5000; Lot #s 106245 -107291. VN2102; Lot #200349. AF1000, AF2000, AF3000, AF4000, AF5000, BT2000, BT3000, BT4000, BT5000, BVM700, CPRM2000, CPRM3000, PRO-1000, PRO-2000, SC7000, SC8020, VN2000, VN3000, VN4000; Lot #s 107029 -107634. VN2002; Lot # 200492. SC8000, SC9000; Lot #s 101441 -107461. CPRM1000; Lot #s 99523 -107315.
Recalling Firm/ Manufacturer	Ventlab LLC 2710 Northridge Dr Nw Suite A Grand Rapids, Michigan 49544-9112
Manufacturer Reason for Recall	The pop-off valve in the defective devices remain open and a squeeze of the bag may not generate enough force to force the duck bill valve open and therefore no air will be delivered to the victim.
FDA Determined Cause [2]	CHANGE CONTROL (GMP - GOOD MANUFACTURING PRACTICE): Process Change Control
Action	The firm, Ventlab, issued a press dated May 14, 2014, stating Ventlab, LLC has initiated a voluntary medical device removal of a limited number of Ventlab" Resuscitator Bags. The bag series and lot numbers were included in a table as well as manufacture dates. In addition, Ventlab, LLC sent an "URGENT: MEDICAL DEVICE PRODUCT REMOVAL IMMEDIATE ACTION REQUIRED" letter dated May 19, 2014 to its distributors and customers. The letter described the product, problem and actions to be taken. The customers were instructed to review and examine their inventory for affected product; stop using them and immediately contact Ventlab, LLC for further instructions on the return of these products; and if product was further distributed, identify their customers/consignees and notify them of this product removal. The customers were also instructed to complete and return the attached Return Response Form via fax at 1-800-400-8820, Attn: Quality Department, or email to: PFA@ventlab.com as soon as possible and inform all affected personnel of this removal. Ventlab will send new corrected replacement resuscitation bags to customers once you return the affected product. If you have any questions regarding this action, please call Ventlab at 1-800-237-5481 between the hours of 8:30 AM to 5:00 PM (EST) Monday through Friday, or 1-844-635-5326 or via e-mail at PFA@ventlab.com.