Class 2 Device Recall HeartStart FR3 Defibrillator

Date Initiated by Firm: October 10, 2018
Create Date: October 18, 2018
Recall Status: Open, Classified
Recall Number: Z-0175-2019
Recall Event ID: 81134223
PMA Number: P16002824
Product Classification: Automated external defibrillators (non-wearable) - Product Code MK225
Product: Philips HeartStart FR3 Defibrillator. Model: 861388, 861389

Product Usage:
The HeartStart FR3 is used to treat suspected victims of ventricular fibrillation (VF), the most common cause of sudden cardiac arrest (SCA), and certain ventricular tachycardia (VTs). Both models are used with disposable pads applied to potential victims of SCA with the following symptoms: 1) Unresponsiveness 2) Absence of normal breathing. The HeartStart FR3 is intended for adults and children over 55 pounds (25kg) or 8 years old. Both models 861388 and 861389 are also intended for children under 55 pounds (25kg) or 8 years old when used with the optional Infant/Child Key. If the Infant/Child Key is not available, or you are uncertain of the child’s age or weight, do not delay treatment. Device not sterile and not implantable.


https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=167498
Recalling Firm/ Manufacturer
Phelps Electronics North America Corp.
22100 Bothell Everett Hwy
Bothell WA 98021-8431

For Additional Information Contact
Philips Customer Services
1-800-722-9377

Manufacturer Reason for Recall
Automated external defibrillators may not fully meet IPX5 water ingress specification. The device may fail to function should water intrusion occur.

FDA Determined Cause
Device Design

Action
On 10/10/2018, Urgent Medical Device Recall notices, which include Field Safety Notices, were mailed via certified mail to U.S. customers. The recalling firm’s Key Markets are responsible for distributing the letters outside of the U.S. Firm is asking customers to follow the Action to be Taken by Customer/User section of the Medical Device Correction Notification/Field Safety Notice: 1) Identify the AEDs affected by this Field Safety Notice by checking the serial numbers. 2) You may continue to use your present device until a replacement AED is provided from the firm if you take precautions to prevent your device from being subjected to a pressurized water stream. 3) Please ensure that any owner or program manager of an affected device is promptly made aware of this notification. If you have transferred the device to another person, please forward a copy of this notice to that person and notify the recalling firm of this transfer as soon as possible. Customers with additional questions can call the following number for assistance: 1-800-263-3342 option 5

Quantity in Commerce
432

Distribution
Worldwide Distribution - U.S Nationwide in the states of: GA, MO, IN, FL, NY, HI, CA, LA, WA, IL, NE; Foreign (OUS): Australia, Austria, Belgium, Canada, France, Germany, Hong Kong, Italy, Japan, Kazakhstan, Netherlands, Norway, Spain, Switzerland, Taiwan, United Kingdom.
Total Product Life Cycle  TPLC Device Report

1 A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls.

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

3 The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

Links on this page:
4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
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23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&amp;event_id=81134
24. /scripts/cdrh/cfdocs/cfpma/pma.cfm?ID=P160028
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10/24/2018