Class 2 Device Recall HeartStart MRx

Date Initiated by Firm: July 16, 2019
Create Date: September 06, 2019
Recall Status: Open, Classified
Recall Number: Z-2488-2019
Recall Event ID: 83576
510(K)Number: K063375
Product Classification: Automated external defibrillators (non-wearable) - Product Code MK

Product: HeartStart MRx Monitor/Defibrillator
Model # M3535A - Product Usage: The HeartStart MRx is a lightweight, portable external defibrillator, offering two modes of operation for defibrillation: manual mode and semi-automatic mode (AED). In manual mode, the HeartStart MRx is a full featured manual defibrillator, designed for use by clinicians trained in Advanced Cardiac Life Support (ACLS). Manual operation allows users to select energy levels for external and internal defibrillation. Users may also perform synchronized cardioversion. Non-invasive external pacing is a device option. In AED mode, the HeartStart MRx allows the provider who is trained in Basic Life Support (BLS) to provide defibrillation therapy. The device analyzes a patient's rhythm and advises the user to deliver a shock. Voice prompts guide the user through the defibrillation process by providing instructions and patient information. The voice prompts are reinforced by messages that appear on the display. In both modes of operation, the HeartStart MRx utilizes impedance compensating biphasic truncated exponential therapy waveform. The HeartStart MRx can also be used for ECG monitoring of a patient using 3, 5 or 12 lead cables.

Code Information: Lot/ Serial # US00539461, US00539462
| Recalling Firm/Manufacturer | Philips North America, LLC  
|                           | 3000 Minuteman Rd  
|                           | Andover MA 01810-1032 |
| For Additional Information Contact | Philips Customer Services  
|                               | 978-659-3000 |
| Manufacturer Reason for Recall | Non-conforming devices are identified, which may not have been included in prior field actions and may not have had a number of corrections applicable to these devices. |
| FDA Determined Cause | Other |
| Action | 1. Locate the MRx devices M3535A with the serial numbers US00539461 and US00539462.  
| | 2. Remove them from clinical use and quarantine these two devices in a secure location.  
| | 3. A Philips representative will contact you to arrange for the removal of the affected HeartStart MRx devices and return them to the factory.  
| If you need further information or support concerning this notification, please contact your local Philips representative or call us at 1-800-722-9377. |
| Quantity in Commerce | 2 units |
| Distribution | US Nationwide distribution in the state of MA. |
| 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.

510(K) Database | 510(K)s with Product Code = MKJ and Original Applicant = PHILIPS MEDICAL SYSTEMS