Class 2 Device Recall HeartStart MRx

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Date Initiated by Firm	July 16, 2019
Create Date	September 06, 2019
Recall Status[1]	Open[3], Classified
Recall Number	Z-2488-2019
Recall Event ID	83576[23]
510(K)Number	K063375[24]
Product Classification	Automated external defibrillators (non-wearable)[25] - **Product Code** MKJ[26]
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 [2]	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[27]

[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[28].

[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[29]

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21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=83576
24. /scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K063375
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=MKJ
26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=MKJ
27. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=MKJ
28. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm
29. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=MKJ&knumber=&applicant=PHILIPS%20MEDICAL%20SYSTEMS

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21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=83576
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