FDA

Class 2 Device Recall HeartStart MRx Monitor/Defibrillator

See Related Information[22]

Date Initiated by Firm	May 03, 2018
Create Date	May 30, 2018
Recall Status[1]	Open[3], Classified
Recall Number	Z-2035-2018
Recall Event ID	79982[23]
510(K)Number	K063375[24]
Product Classification	Automated external defibrillators (non-wearable)[25] - **Product Code** MKJ[26]
Product	HeartStart MRx Monitor/Defibrillator, Model No. M3535A (861288), M3536A (861289) Product Automated external defibrillators (non-wearable) Product Usage: The HeartStart MRx is for use for the termination of ventricular tachycardia and ventricular fibrillation. The device is for use by qualified medical personnel trained in the operation of the device and qualified by training in basic life support, advanced cardiac support, or defibrillation. It must be used by or on the order of a physician.
Code Information	US00588464, US00588657, US00589878, US00591080, US00593861
Recalling Firm/ Manufacturer	Philips Electronics North America Corporation 3000 Minuteman Rd Andover MA 01810-1032
For Additional Information Contact	Philips Customer Services 800-722-9377
Manufacturer Reason for Recall	The MRx monitor/defibrillators could fail to charge because the therapy printed circuit board may have been loaded with an incorrect electronic component. Failure to charge could potentially cause therapy to be interrupted or delayed.
FDA Determined Cause [2]	Employee error
Action	On May 3, 2018, the firm issued an Urgent Amended Medical Device Correction notice to affected customers via certified mail. Customers were reminded that they were previously notified in April 2016 regarding the same issue. At that time, the firm committed to providing a replacement for all affected MRx units. The May 2018 notification was sent only to remaining customers who had not yet received a replacement device. Those customers were informed that due to the product being discontinued, their affected units would receive a replacement therapy board instead of a replacement unit. Customers were informed that they could continue to use their MRx prior to repair. But, if they observe a red X in the Ready for Use indicator, to follow the troubleshooting instructions in the MRx IFU. They were also advised that they would be contacted by Philips to schedule the repair of the device. If the customer has already returned their unit but has not yet received a replacement, they were advised that Philips will be replacing the therapy board, not the entire device. If you need further information or support concerning this notification, please contact your local Philips