FDA

Class 2 Device Recall HeartStart FR3 Defibrillator

See Related Information 22

Date Initiated by Firm	October 10, 2018
Create Date	October 18, 2018
Recall Status[1]	Open[3], Classified
Recall Number	Z-0175-2019
Recall Event ID	81134[23]
PMA Number	P160028[24]
Product Classification	Automated external defibrillators (non-wearable)[25] - **Product Code** MKJ[26]
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.
Code Information	Serial Numbers of affected AEDs begin with C16J, C16K, C17A, or C17B. Serial Numbers: C17B-00171 C17A-01227 C17A-01349 C17A-01361 C17B-00322 C17B-00323 C17B-00360 C17B-00172 C16K-01024 C17A-01356 C17A-01382 C17B-00038 C17A-01152 C16K-00726 C17A-01154 C17B-00101 C17B-00102 C17B-00104 C17B-00105 C17B-00107 C17B-00109 C17B-00110 C17B-00111 C17B-00112 C17B-00113 C17B-00114 C17B-00115 C17B-00116 C17B-00117 C17B-00118 C17B-00119 C17B-00125 C17B-00127 C17B-00132 C17B-00133 C17B-00143 C17B-00145 C17B-00158 C17B-00159 C17B-00160 C17B-00163 C16K-00495 C16K-00952 C16K-01029 C17B-00025 C17B-00057 C17B-00059 C17B-00069 C17B-00070 C17B-00071 C17B-00074 C17B-00077 C17B-00082 C17B-00083 C17B-00084 C17B-00089 C17B-00090 C17B-00098 C17B-00173 C17B-00178 C17B-00324 C17B-00120 C17B-00122 C17B-00123 C17B-00124 C17B-00126 C17B-00128 C17B-00129 C17B-00130 C17B-00131 C17B-00134 C17B-00135 C17B-00136 C17B-00137 C17B-00138 C17B-00139 C17B-00140 C17B-00141 C17B-00149 C17B-00150 C17B-00151 C17B-00152 C17B-00153 C17B-00154 C17B-00155 C17B-00156 C17B-00161 C17B-00167 C17B-00169 C17B-00170 C17B-00174 C17B-00175 C17B-00176 C17B-00177 C17B-00179 C17B-00181 C17B-00183 C17B-00185 C17B-00186 C17B-00188 C17B-00189 C17B-00191 C17B-00192 C17B-00193 C17B-00194 C17B-00195 C17B-00196 C17B-00197 C17B-00198 C17B-00199 C17B-00200 C17B-00201 C17B-00202 C17B-00203 C17B-00204 C17B-00206 C17B-00207 C17B-00209 C17B-00210 C17B-00213 C17B-00215 C17B-00216 C17B-00218 C17B-00219 C17B-00223 C17B-00225 C17B-00226 C17B-00227 C17B-00228 C17B-00229 C17B-00232 C17B-00240 C17B-00243 C17B-00244 C17B-00245 C17B-00246 C17B-00247 C17B-00248 C17B-00255 C17B-00256 C17B-00257 C17B-00258 C17B-00259 C17B-00260 C17B-00261 C17B-00263 C17B-00264 C17B-00265 C17B-00266 C17B-00277 C17B-00278 C17B-00283 C17B-00287 C17A-01261 C17A-01262 C17A-01263 C17A-01265 C17A-01277 C17A-01292 C17A-01293 C17A-01295 C17A-01341 C17A-01343 C17A-01351 C17A-01354 C17A-01355 C17A-01357 C17A-01359 C17A-01360 C17A-01362 C17A-01366 C17A-01368 C17A-

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Recalling Firm/ Manufacturer	Philips Electronics North America Corp. 22100 Bothell Everett Hwy *Bothell* WA 98021-8431
For Additional Information Contact	Philips Customer Services *1800-722-9377*
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 [2]	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
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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.

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