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Class 2 Device Recall Infant Radiant Warmer

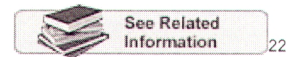


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Class 2 Device Recall Infant Radiant Warmer



Date Initiated by Firm	May 05, 2017
Date Posted	May 19, 2017
Recall Status ¹	Open ³ , Classified
Recall Number	Z-2323-2017
Recall Event ID	77287 ²³
510(K)Number	K963058 ²⁴ K921766 ²⁵ K884160 ²⁶ K851449 ²⁷ K840858 ²⁸
Product Classification	Warmer, infant radiant ²⁹ - Product Code FMT ³⁰
Product	Infant Warmer System (IWS)
Code Information	Medical device listing number: D103053, D103054, D103056, D103057, D183529
Recalling Firm/Manufacturer	GE Healthcare, LLC 3000 N Grandview Blvd Waukesha WI 53188-1615
For Additional Information Contact	800-437-1171
Manufacturer Reason for Recall	GE Healthcare has recently become aware of a potential safety issue related to loose screws in the Heater Head of the Infant Warmer System (IWS). Hot screws from the Heater Head of the IWS could fall onto the bed if the Heater Head assembly has been improperly serviced. This situation can be clinically hazardous because thermal injury to a patient could result. Two injuries have been reported as a result of this issue.
FDA Determined Cause ²	Under Investigation by firm
Action	GE Healthcare sent an Urgent Medical Device Correction letter dated May 5, 2017, to all affected customers. The letter identified the product the problem and the action needed to be taken by the customer. Product Correction : Attached to this letter, we provide instructions as part of a Service Manual Addendum on how to correct the issue. Please add this new Addendum to the Service Manual of your device(s) and train the affected users accordingly. Please acknowledge that you have received this letter and that you understand that an action needs to be taken on your part to correct this issue by filling out and returning the attached Customer Response form. If you have any questions or concerns regarding this notification, please contact GE Healthcare Service at 1-800-437-1171 or your local Service Representative. Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately per the contact information above.
Quantity in Commerce	34986
Distribution	Worldwide Distribution - USA (nationwide) Distribution.
Total Product Life Cycle	TPLC Device Report ³¹