Date Initiated by Firm
May 05, 2017

Date Posted
May 19, 2017

Recall Status
Open, Classified

Recall Number
Z-2323-2017

Recall Event ID
77287

510(K) Number
K963058, K921766, K884160, K851449, K840658

Product Classification
Infant, infant radiant, Product Code FMT

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
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