Class 2 Device Recall Hitachi Echelon Oval MRI system

Date Posted: September 02, 2014
Recall Status: Open
Recall Number: Z-2564-2014
Recall Event ID: 687588
Premarket Notification 510(K) Number: K113145
Product Classification: System, Nuclear Magnetic Resonance Imaging - Product Code LNH
Product: Hitachi Echelon Oval MRI system is a diagnostic imaging device (one unit per package) and is intended to provide the physician with physiological and clinical information, obtained non-invasively and without the use of ionizing radiation.
Code Information: Product Codes: Y001, Y002, Y003, Y004, Y005, Y006, Y007, Y008, Y009, Y010, Y011, Y012, Y014, Y015, Y016, Y101, Y102, Y103, Y105, and Y551. To be updated as firm submits information.
Recalling Firm/Manufacturer: Hitachi Medical Systems America Inc, 1959 Summit Commerce Park, Twinsburg, Ohio 44087-2371
For Additional Information Contact: Douglas Thistlethwaite, 330-425-1313 Ext. 3720
Manufacturer Reason for Recall: The Gradient Coil was found to have a failure mode that allowed it to overheat and become a burn hazard.
FDA Determined Cause: DESIGN: Device Design
Action: Letters will be sent to customers. Hitachi Service will be sent to each site to exchange the Gradient Coil Assembly.
Quantity in Commerce: 39 systems
Distribution: States receiving product: CA, DE, FL, ID, KS, KY, MD, MS, NY, OH, and WY. Foreign locations: Japan, Brazil, France, Germany, Kyrgyzstan
Total Product Life Cycle: TPLC Device Report

1 For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.56
2 Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database: 510(K)s with Product Code = LNH and Original Applicant = HITACHI MEDICAL SYSTEMS AMERICA, INC.

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