Class 2 Recall
Hitachi Echelon Oval MRI system

See Related Information[22]

Date Posted	September 02, 2014
Recall Status[1]	Open
Recall Number	Z-2564-2014
Recall Event ID	68758[23]
Premarket Notification 510(K) Number	K113145[24]
Product Classification	System, Nuclear Magnetic Resonance Imaging[25] - **Product Code** LNH[26]
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 Y951. 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 [2]	DESIGN: Device Design
Action	Letters will be sent to customers. Hatachi Serivce will be sent to each site to exchange the Gradient Coil Assembly.
Quantity in Commerce	39 systems
Distribution	States reciving 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[27]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[28]
[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.[29]

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1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain