FDA

Class 2 Device Recall GE Healthcare SIGNA Voyager and SIGNA Voyager Premier

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See Related Information 22

Date Initiated by Firm	December 23, 2021
Create Date	February 09, 2022
Recall Status[1]	Open[3], Classified
Recall Number	Z-0599-2022
Recall Event ID	89376[23]
510(K)Number	K161567[24] K192426[25]
Product Classification	System, nuclear magnetic resonance imaging[26] - **Product Code** LNH[27]
Product	GE Healthcare MR superconducting magnets, a component of GE Healthcare SIGNA Voyager and SIGNA Voyager Premier Edition system, nuclear magnetic resonance imaging system.
Code Information	All systems.
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	The magnetic resonance systems could potentially have a cryogen ventilation system that does not meet the venting requirements.
FDA Determined Cause [2]	Process control
Action	The recalling firm issued letters dated 12/23/2021 via FedEx explaining the safety issue and the actions to be taken by the customer/user. The actions say that the customer can continue to use the system as normal but they are to follow the instructions listed in the letter and to ensure the system is inspected either by GE Healthcare or the organization who installed their ventilation system to confirm it complies with the safety requirements for ventilation. The customer was requested to complete the workflow which was to be accessed through a QR code or link in the letter within the Medical Device Notification Acknowledgement Response Required form. It was to be returned no later than 30 days from receipt. The customer is also told it is important they continue to follow the guidelines outlined in the Safety chapter of their system Operator Manual, including ensuring a procedure is in place to evacuate the patient and personnel from the magnet room should a quench occur.
Quantity in Commerce	17,228 devices total in this field correction
Distribution	Distribution was nationwide, including Puerto Rico and the Virgin Islands. There was also government and military distribution. Foreign distribution was made to Albania, Algeria, Argentina, Armenia, Australia, Austria, Azerbaidjan, Bahrain, Bangladesh, Belarus, Belgium, Bhutan, Bolivia,