Class 2 Recall CT LightSpeed 16

See Related Information[23]

Date Posted	May 15, 2015
Recall Status[1]	Open
Recall Number	Z-1623-2015
Recall Event ID	71167[24]
Premarket Notification 510(K) Number	K013561[25]
Product Classification	System, X-Ray, Tomography, Computed[26] - **Product Code** JAK[27]
Product	CT LightSpeed 16. Catalogue # 2339985. Designed to be a head and whole body CT scanner utilizing a new solid state detector.
Code Information	Mfg Lot or Serial # System ID 00000331100CN8 904223CT 00000345975CN7 409838LS16 00000337343CN8 512OCCT
Recalling Firm/ Manufacturer	GE Healthcare 3000 N Grandview Blvd Waukesha, Wisconsin 53188-1615
For Additional Information Contact	GE Healthcare Service 800-437-1171
Manufacturer Reason for Recall	GE Healthcare has become aware that 3 bolts that secure a power supply to the rotating side of the gantry were over-torqued on certain Lightspeed 16 CT scanners. In the unlikely event that the component becomes loose on the CT gantry during operation, it could result in serious bodily injury if the component were expelled. There were no incidents or injuries reported as a result of this over-t
FDA Determined Cause [2]	DESIGN: Process Design
Action	Consignees were sent a GE Healthcare "Urgent Medical Device Correction" letter GEHC Ref# 25461 dated April 22, 2015. The letter was addressed to Hospital Administrators / Risk Managers, Managers of Radiology/Cardiology, and Radiologists/Cardiologists. The letter described the Safety Issue, Safety Instructions, Affected Product Details, Product Correction and Contact Information. The letter stated that customers can continue to use their device. If the error occurs, then stop using the system and call a service representative to bring the system back into proper operation. For questions contact GE Healthcare Service at 1-800-437-1171 or your local Service Representative.
Quantity in Commerce	3 USA
Distribution	Distributed to the states of FL & TX.
Total Product Life Cycle	TPLC Device Report[28]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[29]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.