Class 2 Device Recall NeuViz 128

See Related Information[22]

Date Initiated by Firm	August 31, 2016
Create Date	December 23, 2016
Recall Status[1]	Open[3], Classified
Recall Number	Z-0876-2017
Recall Event ID	75383[23]
510(K)Number	K121792[24]
Product Classification	System, x-ray, tomography, computed[25] - **Product Code** JAK[26]
Product	NeuViz 128 Multi-slice CT Scanner System with software version 1.0.7.4038+P06 or previous version
Code Information	NeuViz 128 Multi-slice CT Scanner System with, software version 1.0.7.4038+P06 or previous version.
Recalling Firm/ Manufacturer	Neusoft Medical Systems Co., Ltd. NO. 16 Shiji Road Hunnan Industrial Area Shenyang China
For Additional Information Contact	281-453-1205
Manufacturer Reason for Recall	The Firm discovered during contrast agent tracking scan, when the expected concentration of contrast agent is reached, later planned scan may be interrupted. The system must be powered down and restarted to clear the interruption error before scanning can resume.
FDA Determined Cause [2]	Software design
Action	Neusoft Medical Systems Co. Ltd. planned action to bring into compliance. 1.Affected Customers will be notified by letter to provide them a description of the affected device, instructions for using the device prior to correction, hazards associated with the defect, and a statement of corrective actions to be taken at no cost to the owner. 2.Field Service Engineers will visit owner sites to install a software update which resolves the defect. 3.Corrections will be made at no cost to the owner 4.Corrections will be completed by May 11, 2017. CDRH approves the CAP subject to the following conditions: .Notification of all dealers and purchasers is to be made within 15 working days of receipt of this letter in the manner specified in 21 CFR 1003.21 and 1003.22. This office and the Food and Drug Administration (FDA) district office coordinator noted below are to be included in the notification. Further questions please call (281) 453-1205.
Quantity in Commerce	23 units
Distribution	US Distribution
Total Product Life Cycle	TPLC Device Report[27]