Date Initiated by Firm: August 31, 2016
Create Date: December 23, 2016
Recall Status: Open, Classified
Recall Number: Z-0875-2017
Recall Event ID: 7538323
510(K) Number: K12179224
Product Classification: System, x-ray, tomography, computed - Product Code JAK
Product: NeuViz 64 Multi-slice CT Scanner Systems
Code Information: NeuViz 64e, NeuViz 64i with software version 1.0.6.3258 +P04 or previous version.
Recalling Firm/Manufacturer: Neusoft Medical Systems Co., Ltd.
NO. 16 Shijji 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: 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

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=150174