Class 2 Device Recall NeuViz 64 Multislice CT Scanner System

Date Initiated by Firm
May 19, 2017

Create Date
August 28, 2017

Recall Status
Open, Classified

Recall Number
Z-3044-2017

Recall Event ID
77608

510(K)Number
K121972

Product Classification
System, x-ray, tomography, computed - Product Code JAK

Product
Neusoft Medical NeuViz 64 Multi-slice CT Scanner System, including: NeuViz 64e, NeuViz 64i with software version 1.0.6.3258 +P11 or previous version, NeuViz 64En, NeuViz 64In with software version 1.0.7.4021+P11 or previous version.

Product Usage:
The Multi-Slice CT Scanner System can be used as a whole body computed tomography X-ray system featuring a continuously rotating X-ray tube and detector array. The acquired X-RAY transmission data is reconstructed by computer into cross-sectional images of the body from either the same axial plane taken at different angles or spiral planes taken at different angles.

Code Information
NeuViz 64 Multi-slice CT Scanner System, including: NeuViz 64e, NeuViz 64i with software version 1.0.6.3258 +P11 or previous version, NeuViz 64En, NeuViz 64In with software version 1.0.7.4021+P11 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
Software defect

FDA Determined Cause
Software design

Action
Neusoft Medical Systems will bring defect into compliance. The defect will be remedied by updating software. Field Change Order I related to software updated will be released to the affected systems in Aug 2017. The affected systems will be upgraded with updated software in the field free of charge in 6 months after the FCO release.

Quantity in Commerce
234

Distribution
US Nationwide distribution

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=156762

9/5/2017