

FDA Home³ Medical Devices⁴ Databases⁵

Class 2 Device Recall NeuViz 64 Multislice CT Scanner System

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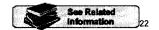
Listing⁹ Events¹⁰

CFR Title 21¹⁶|Radiation-Emitting Products¹⁷|X-Ray Assembler¹⁸|Medsun Reports¹⁹|CLIA²⁰|TPLC²¹

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Class 2 Device Recall NeuViz 64 **Multislice CT Scanner System**



Date Initiated by Firm

May 19, 2017

Create Date

August 28, 2017

Recall Status¹

Open3, Classified

Recall Number

Z-3044-2017

Recall Event ID

77608²³

510(K)Number

K12197224

Product Classification

System, x-ray, tomography, computed²⁵ - Product Code <u>JA</u>K²⁶

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 641n 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 641n with

software version 1.0.7.4021+P11 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

Software defect

FDA Determined Cause 2

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 char e in 6 months after the FCO release.

Quantity in Commerce

234

Distribution

US Nationwide distribution