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



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



<b>Date Initiated by Firm</b>	May 19, 2017
<b>Create Date</b>	August 28, 2017
<b>Recall Status<sup>1</sup></b>	Open <sup>3</sup> , Classified
<b>Recall Number</b>	Z-3044-2017
<b>Recall Event ID</b>	<u>77608</u> <sup>23</sup>
<b>510(K)Number</b>	<u>K121972</u> <sup>24</sup>
<b>Product Classification</b>	<u>System, x-ray, tomography, computed</u> <sup>25</sup> - <b>Product Code</b> <u>JAK</u> <sup>26</sup>
<b>Product</b>	<p>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</p> <p><b>Product Usage:</b>                      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.</p>
<b>Code Information</b>	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
<b>Recalling Firm/Manufacturer</b>	Neusoft Medical Systems Co., Ltd. NO. 16 Shiji Road Hunnan Industrial Area Shenyang China
<b>For Additional Information Contact</b>	281-453-1205
<b>Manufacturer Reason for Recall</b>	Software defect
<b>FDA Determined Cause<sup>2</sup></b>	Software design
<b>Action</b>	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.
<b>Quantity in Commerce</b>	234
<b>Distribution</b>	US Nationwide distribution