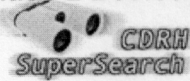


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**Class 2 Device Recall NeuViz 64**

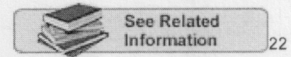


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**Class 2 Device Recall NeuViz 64**



<b>Date Initiated by Firm</b>	August 31, 2016
<b>Create Date</b>	December 23, 2016
<b>Recall Status<sup>1</sup></b>	Open <sup>3</sup> , Classified
<b>Recall Number</b>	Z-0875-2017
<b>Recall Event ID</b>	<u>75383</u> <sup>23</sup>
<b>510(K)Number</b>	<u>K121792</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>	NeuViz 64 Multi-slice CT Scanner Systems
<b>Code Information</b>	NeuViz 64e, NeuViz 64i with software version 1.0.6.3258 +P04 or previous version. NeuViz 64En, NeuViz 641n with software version 1.0.7.4021+P05 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>	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.
<b>FDA Determined Cause<sup>2</sup></b>	Software design
<b>Action</b>	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.
<b>Quantity in Commerce</b>	23 units
<b>Distribution</b>	US Distribution
<b>Total Product Life Cycle</b>	<u>TPLC Device Report</u> <sup>27</sup>