



NEUSOFT MEDICAL SYSTEMS CO., LTD.
% Shao Xiancheng
R&A
No. 16, Shiji Road
Hunnan Industrial Area
Shenyang, Liaoning 110179
P R CHINA

December 7, 2017

Re: K171198
Trade/Device Name: NeuViz 16 Essence Multi-Slice CT Scanner System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: November 6, 2017
Received: November 13, 2017

Dear Shao Xiancheng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

 For

Robert Ochs, Ph.D.

Director

Division of Radiological Health

Office of In Vitro Diagnostics

and Radiological Health

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K171198

Device Name

NeuViz 16 Essence Multi-Slice CT Scanner System

Indications for Use (Describe)

The NeuViz 16 Essence 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.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) Summary

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.92

General Information:

Manufacturer: Neusoft Medical Systems Co., Ltd.
No.177-1 Chuangxin Road, Hunnan District,
Shenyang, Liaoning, China, 110167.

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510(k) Summary Date of Preparation: November 6, 2017

Device Name and Classification:

Trade Name: NeuViz 16 Essence Multi-Slice CT Scanner System
Common Name: CT Scanner
Regulation: 21 CFR 892.1750
Classification Name: Computed tomography x-ray system
Product Code: JAK
Classification: Class II
Performance Standard: 21 CFR Subchapter J, Federal Diagnostic X-ray Equipment Standard

Primary Predicate device:

Trade Name: NeuViz 16 Multi-Slice CT Scanner System
510(k) number: K092742
Clearance Date: 09/22/2009
Regulation: 21 CFR 892.1750
Classification Name: Computed tomography x-ray system
Product Code: JAK
Classification: Class II
Manufacturer: Neusoft Medical Systems Co., Ltd.

Reference Device:

Trade Name: NeuViz 128 Multi-Slice CT Scanner System
510(k) number: K151383
Clearance Date: 11/04/2015
Regulation: 21 CFR 892.1750
Classification Name: Computed tomography x-ray system
Product Code: JAK
Classification: Class II
Manufacturer: Neusoft Medical Systems Co., Ltd.

Safety and Effectiveness information

Indications for use:

The NeuViz 16 Essence 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.

Device Description:

The NeuViz 16 Essence Multi-Slice CT Scanner System is composed of a gantry, a patient couch, an operator console and includes image acquisition hardware and software, and associated accessories. It is designed to be a head and whole body X-ray computed tomography scanner which features a continuously rotating tube-detector system and functions according to the fan beam principle.

The system provides the filter back-projection (FBP) and iterative reconstruction algorithm(ClearView cleared in K133373) to reconstruct images. The end user can choose to apply either ClearView or the FBP to the acquired raw data.

The system software is an interactive program used for X-ray scan control, image reconstruction, and image archive/evaluation. It provides the following digital image processing and visualization tools:

- Support following scan speed: 0.5s、 0.6s、 0.75s、 1.0s、 1.5s、 2.0s.
- Surview scan
- Dual surview
- Spiral scan
- Axial scan
- Image reconstruction
- Plan scan
- Patient information management
- Patient information registration
- Protocol selection
- O-Dose
- Bolus tracking
- SAS
- Home
- Film
- Report
- 2D
- MPR
- 3D
- VE(Virtual Endoscopy)
- Vessel Analysis
- Dicom Viewer
- Bar code Reader
- Dual Monitor
- Continuous CT
- ClearView
- Dental Analysis
- Virtual Colonoscopy
- Brain Perfusion
- Body Perfusion
- Lung Nodule Analysis

- Lung Density Analysis
- CTDSA
- Tumor Assessment

Statement of Substantial Equivalence:

The NeuViz 16 Essence Multi-Slice CT Scanner System has the same indications for use as the predicate device, NeuViz 16 Multi-Slice CT Scanner System (K092742). The NeuViz 16 Essence is a computed Tomography X-Ray System intended to produce images of the body by computer reconstruction of x-ray transmission data taken at different angles and planes. The subject device does not have significant changes in technological characteristics when compared to the predicate device. The subject device and predicate device are the same in regards to:

- Detector/Tube system that can rotate continuously. The Tube emits X-ray beam of fan shape, detector system with multiple channels;
- Low voltage slip ring and On-Board HV Generator;
- Parallel data acquisition, simultaneous scan and image reconstruction;
- Gantry that may be tilted forward or backward;
- Patient Couch that can be elevated or lowered;
- Computerized control of scan and other operations;
- Computerized image reconstruction and post processing;
- Digitalized display, storage and output of data/image.

The subject device and the reference device, NeuViz 128 Multi-Slice CT Scanner System (K151383) are the same in regard to most of application features.

A complete comparison table is included in this submission. The following table shows a brief comparison of the application features, including both similarities and differences among the subject, the predicate and the reference devices.

NeuViz 16 Essence	NeuViz 16	NeuViz 128
O-Dose	×	✓
Bolus tracking	✓	✓
SAS	✓	✓
Home	×	✓
Film	✓	✓
Report	✓	✓
2D	×	✓
MPR	✓	✓
3D	✓	✓
VE(Virtual Endoscopy)	✓	✓
Vessel Analysis	✓	✓
Dicom Viewer	×	✓
Bar code Reader	✓	✓
Dual Monitor	×	✓

Continuous CT	√	√
ClearView	×	√
Dental Analysis	√	√
Virtual Colonoscopy	×	√
Brain Perfusion	√	√
Body Perfusion	×	√
Lung Nodule Analysis	×	√
Lung Density Analysis	×	√
CTDSA	×	√
Tumor Assessment	×	√
Comparison		
<p>“√” symbol means the comparable type and substantially equivalent to the contrasted devices. “x” symbol means the new clinical functionality. Including O-Dose, ClearView, Virtual Colonoscopy, Body Perfusion, Lung Nodule Analysis, Lung Density Analysis, CTDSA and Tumor Assessment, these advanced image-processing software features were drawn from the NeuViz 128 without any change.</p>		

According to the comparison based on the requirements of 21 CFR 807.87, we stated that these devices are substantially equivalent.

Nonclinical Testing:

The safety and effectiveness of the NeuViz 16 Essence was assured by adherence to Good Manufacturing Practices(GMP) 21CFR 820 and to International Standards ISO 13485:2003. This device is in conformance with the applicable parts of the following standards:

- ANSI/AAMI ES60601-1:2005/(R) 2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 medical electrical equipment -- part 1: general requirements for basic safety and essential performance
- IEC 60601-1-2: 2007, Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-1-3: 2013, Medical Electrical Equipment - Part 1-3: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Radiation Protection In Diagnostic X-Ray Equipment
- IEC 60601-1-6: 2013, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-2-28: 2010, Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
- IEC 60601-2-44: 2012, Medical Electrical Equipment - Part 2-44: Particular Requirements For The Basic Safety And Essential Performance Of X-Ray Equipment For Computed Tomography
- IEC 60825-1:2007, Safety of laser products - part 1: equipment classification, and requirements
- IEC 61223-3-5: 2004, Evaluation and routine testing in medical imaging departments - Part 3-5: Acceptance tests - Imaging performance of computed tomography X-ray equipment
- AAMI ANSI IEC 62304:2006, Medical device software - Software life-cycle processes
- IEC 62366:2014, Medical Devices - Application Of Usability Engineering To

Medical Devices

- ISO 10993-1: 2009, Biological evaluation of medical devices - part 1: evaluation and testing within a risk management process.
- ISO 14971:2007, Medical devices – Application of risk management to medical devices
- NEMA PS 3.1 - 3.20 (2016), Digital Imaging And Communications In Medicine (DICOM) Set
- NEMA XR 25: 2010, Computed tomography dose check
- NEMA XR 28: 2013, Supplemental Requirements for User Information and System Function Related to Dose in CT

Additionally, this device complies with all applicable requirements of the radiation safety performance standards, as outlined in 21 CFR §1010 and §1020.

Risk management is ensured via a hazard analysis which is used to identify potential hazards. These potential hazards are controlled during product development, and verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Neusoft adheres to recognized and established industry practice and standards.

Software safety is assured by the company procedures that conform to accepted practices. Quality assurance procedures are adhered to, and meeting the specifications and functional requirements is demonstrated via testing. Testing included functional, smoke and regression tests. The vast majority of tests passed our testing criteria. Any defects found or reported were either fixed or logged in the Unresolved Anomalies report included with this submission and annotated as to any impact on safety or effectiveness including applicable workarounds. The traceability between design requirements, design specifications, testing requirements, and relevant hazards with the implementation and testing of the mitigations are described in the Traceability Matrix. The Traceability Matrix also shows the overall test results per requirement and per hazard mitigation.

Cybersecurity requirements is assured by implementing a process of preventing unauthorized access, modifications, misuse or denial of use, or the unauthorized use of information that is stored, accessed, or transferred from a medical device to an external recipient. Cybersecurity information in accordance with guidance document “Content of Premarket Submissions for Management of Cybersecurity Medical Devices issues on October 2, 2014” is included within this submission.

Software Documentation for a Moderate Level of Concern, per the FDA guidance document, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document” issued on May 11, 2005, is also included as part of this submission.

Verification and validation activities (including performance testing, safety testing and simulated use testing) was performed. Some of the bench tests included the sag and the speed of patient support table, the gantry wobble, CT image quality metrics testing including CT number accuracy and uniformity, MTF, noise, slice sensitivity profiles and CTDI. Sample images were provided to show the performance of the system in presence of implants.

The results of these tests demonstrate that the subject device performs as intended. The result of all conducted testing was found acceptable to support the claim of substantial equivalence.

Clinical Testing:

The clinical validation plan identified the tasks, deliverables, methodology, requirements and the resources for validation of the intended use and meets customer needs. The clinical validation covered requirements related to clinical workflows and features. The validation was executed as planned and acceptance criteria met for each requirement. All validation tests demonstrate the safety and effectiveness of NeuViz 16 Essence.

The results of the validation are available in the Clinical Validation Summary. Two CT clinical specialists of Neusoft validated the system under simulative clinical circumstances. An image evaluation was performed to evaluate images of the brain, chest, abdomen and spine/extremities of the body area. Images were scored using a 5 point Likert scale by a qualified radiologist. The Results indicated that the images were of diagnostic quality. The proposed NeuViz 16 Essence can be used as defined in its clinical workflow and intended use.

Conclusions:

The NeuViz 16 Essence performs in a manner similar to and is intended for the same use as the predicate device, as indicated in product labeling. Based upon this information, conformance to standards, successful completion of software validation, application of risk management and design controls and the performance data presented in this submission it is concluded that the subject device is substantially equivalent in safety and effectiveness to the predicate device. The comparison of technological characteristics, non-clinical performance data, software validation and clinical images demonstrates that the subject device is as safe and effective when compared to the predicate device that is currently marketed for the same intended use.

According to the comparison based on the requirements of 21.CFR 807.87, Neusoft believes that the subject device and the predicate device are substantially equivalent.