October 11, 2023

Neusoft Medical Systems Co., Ltd.
℅ Tian Yuehui
Q&R Manager
No. 177-1 Chuangxin Road, Hunnan District
SHENYANG, LIAONING 110167
CHINA

Re: K230220
Trade/Device Name: NeuViz 128 Multi-Slice CT Scanner System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: September 8, 2023
Received: September 11, 2023

Dear Tian Yuehui:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230220

Device Name
NeuViz 128 Multi-Slice CT Scanner System

Indications for Use *(Describe)*
The NeuViz 128 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

1. General Information:

Manufacturer:	Neusoft Medical Systems Co., Ltd. No.177-1 Chuangxin Road, Hunnan District, Shenyang, Liaoning, China, 110167.
Contact person:	Tian Yuehui Title : Q&R Manager Tel : 86-24-23358105 E-Mail : tianyh@neusoftmedical.com
Date of Preparation:	October 8, 2023

2. Device Name and Classification:

Trade Name:	NeuViz 128 Multi-Slice CT Scanner System
Common Name:	CT Scanner
Regulation Number:	21 CFR 892.1750
Regulation Name:	Computed tomography x-ray system
Product Code:	JAK
Classification:	Class II
Performance Standard:	21 CFR Subchapter J, Federal Diagnostic X-ray Equipment Standard

3. Predicate device:

Trade Name:	NeuViz 128 Multi-Slice CT Scanner System
510(k) number:	K151383
Clearance Date:	11/04/2015
Regulation Number:	21 CFR 892.1750
Classification Name:	Computed tomography x-ray system
Product Code:	JAK
Classification:	Class II
Manufacturer:	Neusoft Medical Systems Co., Ltd.
Recall Information:	All predicate device recalls have been considered in the subject device design

4. Reference Device:

Trade Name:	NeuViz Prime Multi-Slice CT Scanner System
510(k) number:	K171201
Clearance Date:	09/13/2017
Regulation Number:	21 CFR 892.1750

Classification Name:	Computed tomography x-ray system
Product Code:	JAK
Classification:	Class II
Manufacturer:	Neusoft Medical Systems Co., Ltd.

5. Reason for submission:

Modification of existing medical device

6. Device Description:

The proposed NeuViz 128 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.

Same as the predicate, The gantry has a 72cm bore with a maximum FOV of 50 cm and available rotation speeds are still 0.374s,0.5s, 0.6s,0.8s,1.0s,1.5s,2.0s per 360° rotation.

The proposed NeuViz 128 has three types of reconstruction methods available: FBP(filter back-projection), ClearView(iterative reconstruction algorithm), and ClearInfinity . ClearInfinity is a new added recon mode where the system uses a trained deep learning neural network to generate noise reduction images and improve low contrast detectability with reduced dose compared with standard FBP recon mode.

7. Indications for use

The NeuViz 128 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.

8. Indications for use comparison

The indications for use of the proposed NeuViz 128 is the same as that of the predicate device.

9. Comparison of Technological Characteristics with the Predicate Devices

The proposed NeuViz 128 includes most of the available features on the current production predicate device and employs the same fundamental technologies as those of the predicate device.

A tabular summary of the comparable hardware ,software properties and features between the proposed device with predicate device are listed in Table 1and 2 below (modifications are in gray shaded sections).

Table 1:Technical hardware characteristics for subject device compared to the predicate devices.

Hardware property	**Proposed device** **NeuViz 128**	**Predicate device** **NeuViz 128 (K151383)**
Gantry Aperture	720mm	720mm
Gantry Tilt	+/-30°	+/-30°
Gantry Scan Speed（s / 360°）	0.374s、0.5s、0.6s、0.8s、1.0s、1.5s、2.0s	0.374s、0.5s、0.6s、0.8s、1.0s、1.5s、2.0s
Detector Type	Solid-state GOS ceramic	Solid-state GOS ceramic
Detector Number of Detector Rows	64	64
Maximum slices generated per rotation (multislice capability)	128	128
Generator Max. Power	80kW	80kW
Generator mA Range	10mA~667mA	30mA~667mA
Generator kV Settings	80kV, 100kV, 120kV, 140kV	80kV, 100kV, 120kV, 140kV
Tube Focal Spots	0.6×1.2（small） 1.1×1.2（large）	0.6×1.2（small） 1.1×1.2（large）
Tube heat capacity	8.0MHU	8.0MHU
Couch Type/max. moving length/max. table loading/max. horizontal speed	standard couch(option): 211kg/225mm/s long couch(option): 211kg/310mm/s 300kg couch(option):	standard couch: 205kg/160mm/s 300kg couch (option): 300kg/160mm/s

	300kg/225mm/s	
Intelligent Positioning Device (optional)	option for Intelligent Positioning feature	N/A

Table 2: Software characteristics and features for subject device compared to the predicate devices.

Software property and Feature	**Proposed device** **NeuViz 128**	**Predicate device** **NeuViz 128 (K151383)**
Recon FOV	50mm~500mm; Extended FOV 700mm(Optional)	50mm~500mm
Spiral Scan Range of Pitch	0.1-2.1	0.13-1.5
Reconstruction Algorithm	Filtered back-projection (FBP); ClearView; ClearInfinity (Optional);	Filtered back-projection (FBP) ; ClearView
O-Dose	Support	Support
Bolus tracking	Support	Support
SAS	Support	Support
Home	Support	Support
Film	Support	Support
Report	Support	Support
Image Review	Support	Support
MPR	Support	Support
3D	Support	Support
Virtual Endoscopy	Support	Support
Dental Analysis	Support	Support

(Optional)		
Vessel Analysis	Support	Support
DICOM Viewer	Support	Support
Virtual Colonoscopy(Optional)	Support	Support
Brain Perfusion(Optional)	Support	Support
Body Perfusion(Optional)	Support	Support
Lung Nodule Analysis(Optional)	Support	Support
Lung Density(Optional)	Support	Support
Coronary Analysis(Optional)	Support	Support
Cardiac Calcium Scoring(Optional)	Support	Support
Cardiac Function Analysis(Optional)	Support	Support
Cardiac Viewer(Optional)	Support	Support
Fat Analysis(Optional)	Support	Support
CTDSA(Optional)	Support	Support
Tumor Assessment(Optional)	Support	Support
Real-time MPR(Optional)	Support. Real-time MPR reconstruction is a recon mode, in the clinical scanning, automatically generate sagittal or coronal MPR images based on the CT axial images. Reduce secondary loading reconstruction time.	N/A

4D scanning(Optional)	Support. It is a kind of fast spiral perfusion scan.The table top of couch moves back and forth repeatedly in the area of interest when the patient is injected with contrast agent. So as to track the dynamic images of contrast agent changing in the same part at different times.	N/A
Dual Energy Imaging （Prism Imaging）(Optional)	Support. Dual-energy imaging uses two energies during one CT examination, performs image reconstruction of data originated by the two energy separately and then decomposes the two kinds of images into a set of basis images of pre-defined materials (the decomposition parameters are pre-set by the manufacturer) , according to which the next process is conducted.	N/A
Prism Viewer(Optional)	Support Prism Viewer application is used to view and analysis multi energy images. Display a variety of images with different parameters and provide visual tools, to help users to locate the lesion accurately.	N/A
Intelligent Positioning(Optional)	Support. The system collects and displays the natural image information of the human body. The system can use the human body image information to automatically calculates the scanning position according to the scanning protocol and using artificial intelligence technology. At the same time, User can also manually draw the scan frame on the human body Image, And Then, the system calculates the scanning position by the scan frame.	N/A

	According to the scanning protocol, the system can automatically adjust the couch height from intelligence setting. The system support patient position, posture and collision Detection.	
Coronary Motion Clear(Optional)	Support. Coronary Motion Clear function is used to generate image dateset with less motion artefact in coronary area.	N/A
Metal artifact removal(Optional)	MAR,MAR+. MAR/MAR+ stands for metal artifact reduction. It's the post processing algorithm that can remove the artifacts caused by metal or high CT value. MAR method only needs image data, while MAR+ method needs both image data and raw data.	MAR
Arrhythmia Handling(Optional)	Support. Recognize and ignore the arrhythmia R-peak during cardiac scan, and trigger the scan while normal R-peak recognized.	N/A
Auto FOV+(Optional)	Support. Auto FOV is automatically mark the FOV range on the surview image based on AI technology, and the FOV range can be adjusted manually.Supported scan parts include head and lungs	N/A

Any differences in technological characteristics do not raise different questions of safety and effectiveness. Testing and validation is completed. Test results show that the subject device is substantially equivalent to the predicate devices.

Note:

+ Auto FOV has not been thoroughly tested on pediatric under 3 years old. A consultation with a radiologist and a physicist should be made to determine the appropriate scan FOV for perform the particular clinical task.

10. Performance Data

Summary of Non-Clinical Testing:

The device has successfully completed all testing per our quality system as well as addition engineering bench testing in support of this submission. It was designed and is manufactured under the Quality System Regulations of 21 CFR 820 and ISO 13485 .

This device is in conformance with the applicable parts of the following standards:
--ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]
--ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021] Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests [Including Amendment 1 (2021)]
--IEC 60601-1-3 Edition 2.2 2021-01 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 Edition 3.2 2020-07 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
--IEC 60601-2-28 Edition 3.0 2017-06 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 Edition 3.2: 2016 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 Edition 2.0 2007-03 Safety of laser products - Part 1: Equipment classification, and requirements
-- IEC 61223-3-5:2019 Evaluation and routine testing in medical imaging departments - Part 3-5: Acceptance and constancy tests - Imaging performance of computed tomography X-ray equipment
--IEC 62304 Edition 1.1 2015-06 Medical device software - Software life cycle processes
--IEC 62366-1 2020 Medical devices Part 1: Application of usability engineering to medical devices
--ISO 14971:2019 Medical devices – Application of risk management to medical devices
--NEMA XR 25: 2019, 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 analysis and verification/validation activities conducted through bench testing which is included in this submission demonstrate that the established specifications for the device have been met. Additional performance testing, using phantom studies, were conducted to assess the improvements to existing features. Results of all these studies demonstrate that the features included in this submission meet specifications and perform as intended.

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 referenced as for this submission.

Neusoft Medical Systems Co., Ltd conforms to the Cybersecurity requirements 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.

Additional Non-Clinical Testing for ClearView and ClearInfinity

Performance Verification for ClearView*

Engineering bench testing was performed to support substantial equivalence and the product performance claims. The evaluation and analysis used the raw datasets obtained on NeuViz 128 and then applies both ClearView and Filtered Back Projection reconstruction. The content and results of the test are as follows:

Quantitative dose reduction test using the CCT189 and CCT191 MITA IQ LC Phantoms and the channelized Hotelling observer. Compared with FBP, ClearView may enable lower radiation dose of head by 40% to 50% at the same image quality+; Compared with FBP, ClearView may enable lower radiation dose of body by 45% to 60% at the same image quality+.

Quantitative low-contrast resolution improvement test using the CCT189 and CCT191 MITA IQ LC Phantoms and the channelized Hotelling observer. Compared with FBP, ClearView may enable improve low contrast detectability of head by 30% to 35% at the same dose+; Compared with FBP, ClearView may enable improve low contrast detectability of body by 35% to 45% at the same dose+.

Quantitative noise reduction test using the water layer of the QA phantom. Compared with FBP, ClearView may enable reduce image noise up to 55% at the same dose+.

Note:

**ClearView has not been thoroughly tested on advanced post-processing application. A consultation with a radiologist and a physicist should be made to determine the appropriate dose to obtain diagnostic image quality for the particular clinical task Performance Verification for ClearView;*

ClearView has not been thoroughly tested in pediatric population. A consultation with a radiologist and a physicist should be made to determine the appropriate dose to obtain diagnostic image quality for the particular clinical task;

Clinicians or dosimetrists should only be allowed to reduce patient dose in clinical practice.

+ In clinical practice, the use of ClearView may reduce CT patient dose depending on the clinical task, patient size, anatomical location, and clinical practice. A consultation with a radiologist and a physicist should be made to determine the appropriate dose to obtain diagnostic image quality for the particular clinical task. Low Contrast Detectability (LCD),Image Noise were assessed using normal dose comparing ClearView and FBP. The LCD and Image Noise measured in smooth kernel and 0.625 mm slices. The claims are based on ClearView 90% level.

Performance Verification for ClearInfinity*

Engineering bench testing was performed to support substantial equivalence and the product performance claims. The evaluation and analysis used the raw datasets obtained on NeuViz 128 and then applies both ClearInfinity and Filtered Back Projection reconstruction. The content and results of the test are as follows:

Quantitative dose reduction test using the CCT189 and CCT191 MITA IQ LC Phantoms and the channelized Hotelling observer. Compared with FBP, ClearInfinity may enable lower radiation dose of head by 50% to 60% at the same image quality+; Compared with FBP, ClearInfinity may enable lower radiation dose of body by 75% to 85% at the same image quality+.

Quantitative low-contrast resolution improvement test using the CCT189 and CCT191 MITA IQ LC Phantoms and the channelized Hotelling observer. Compared with FBP, ClearInfinity may enable improve low contrast detectability of head by 35% to 65% at the same dose+; Compared with FBP, ClearInfinity may enable improve low contrast detectability of body by 60% to 115% at the same dose+.

Quantitative noise reduction test using the water layer of the QA phantom. Compared with FBP, ClearInfinity may enable reduce image noise up to 90% at the same dose+.

Quantitative improvement of spatial resolution test using the high-contrast test device in the physical layer and water layer of the QA phantom. Compared with FBP, ClearInfinity may enable improve spatial resolution up to 1.88X (88%) at same image noise+.

Note:
** US patient-based testing data for ClearInfinity collected from three sites of* OK *and one site of TX,* a total of 445 clinical cases of 297 independent patients;
ClearInfinity has not been thoroughly tested on advanced post-processing application. A consultation with a radiologist and a physicist should be made to determine the appropriate dose to obtain diagnostic image quality for the particular clinical task Performance Verification for ClearInfinity;
ClearInfinity has not been thoroughly tested in pediatric population. A consultation with a radiologist and a physicist should be made to determine the appropriate dose to obtain diagnostic image quality for the particular clinical task;
Clinicians or dosimetrists should only be allowed to reduce patient dose in clinical practice.

+ In clinical practice, the use of ClearInfinity may reduce CT patient dose depending on the clinical task, patient size, anatomical location, and clinical practice. A consultation with a radiologist and a physicist should be made to determine the appropriate dose to obtain diagnostic image quality for the particular clinical task. Low Contrast Detectability (LCD),Image Noise, Spatial Resolution were assessed using normal dose comparing ClearInfinity and FBP. The LCD and Image Noise measured in smooth kernel and 0.625 mm slices; Spatial Resolution measured in sharp kernel and 0.625 mm slices. The claims are based on ClearInfinity 90% level.

Clinical Image Evaluation for ClearInfinity

The reader study used a total of 30 retrospectively collected clinical cases（Determine the sample size according to Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices）. The raw data from each of these cases was reconstructed with both Filtered Back Projection and ClearInfinity Deep Learning Image Reconstruction. The images generated by the two reconstruction methods of the same raw data are presented to the reader in pairs. Each image was read by 3 board-certified radiologists who provided an assessment of image quality related to diagnostic use according to a 5-point Likert scale. The results of the study indicate that ClearInfinity is equivalent or better than Filtered Back Projection in diagnostic quality.
An additional study used a total of 20 retrospectively collected clinical cases which raw data were processed at simulated low doses to produce low-dose images. Each of the low dose images

was reconstructed with both Filtered Back Projection and ClearInfinity Deep Learning Image Reconstruction. Each image was read by 3 board-certified radiologists who provided an assessment of image quality related to diagnostic use according to a 5-point Likert scale. The results of the study indicate that ClearInfinity is equivalent or better than Filtered Back Projection in diagnostic quality at low doses.

Testing for verification and validation support the claims of substantial equivalence.

Clinical Testing

No Clinical Study is included in this submission.

11. Substantial equivalence Conclusions

Based on the conformance to standards, development under our quality system, and the engineering testing provided, we believe that the modified NeuViz 128 is as safe and effective, and performs in a substantially equivalent manner to the predicate device (K151383)