DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Neusoft Medical Systems Co., Ltd.
% Mr. Tian Yuehui
No. 16, Shiji Road
Hunnan Industrial Area
Shenyang, Liaoning, 110179
CHINA

December 3, 2014

Re: K133373
Trade/Device Name: ClearView
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: October 30, 2014
Received: November 3, 2014

Dear Mr. 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 (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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number（if known）：K133373

Device Name: ClearView

Indications for use：

ClearView is a CT reconstruction software. The end user can choose to apply either ClearView or the filter back-projection (FBP) to the acquired raw data.

Depending on the clinical task, patient size, anatomical location, and clinical practice, the use of ClearView can help to reduce radiation dose while maintaining Pixel noise, low contrast detectability and high contrast resolution. Phantom measurements showed that high contrast resolution and pixel noise are equivalent between full dose FBP images and reduced dose ClearView images. Additionally, ClearView can reduce body streak artifacts by using iterations between image space and raw data space.

A Model Observer evaluation showed that equivalent low contrast detectability can be achieved with less dose using ClearView at highest noise reduction level for thin (0.625 mm) reconstruction slices in MITA body and ACR head phantoms for low contrast objects with different contrasts.

ClearView are not intended to be used in CCT and Pilot.

Prescription Use ____ √ ___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use (21 CFR 801 Subpart C) _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Deices (OIVD)

_____

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k)_____

Section 6

510(K) Summary

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:

Trade Name:	ClearView
Common Name:	ClearView
Classification Name:	21 CFR Part 892.1750 Computed Tomography X-ray System
Classification:	Class II
Performance Standard:	21 CFR Subchapter J, Federal Diagnostic X-ray Equipment Standard
Manufacture:	Neusoft Medical Systems Co., Ltd. No.16 Shiji Road, Hunnan Industrial Area, Shenyang, Liaoning, China, 110179
Distributor:	Neusoft Medical Systems Co., Ltd. No.16 Shiji Road, Hunnan Industrial Area, Shenyang, Liaoning, China, 110179
Submitter:	Contact : Tian Yuehui Title : Manager of Q&R Department Tel : 86-24-83660646 Fax : 86-24-83660563 E-Mail : tianyh@neusoft.com
	Summary prepared : November, 30, 2014

Safety and Effectiveness information

Intended Uses:

ClearView is a CT reconstruction software. The end user can choose to apply either ClearView or the filter back-projection (FBP) to the acquired raw data. Depending on the clinical task, patient size, anatomical location, and clinical practice, the use of ClearView can help to reduce radiation dose while maintaining Pixel noise, low contrast detectability and high contrast resolution. Phantom measurements showed that high contrast resolution and pixel noise are equivalent between full dose FBP images and reduced dose ClearView images. Additionally, ClearView can reduce body streak artifacts by using iterations between image space and raw data space.
A Model Observer evaluation showed that equivalent low contrast detectability can be achieved with less dose using ClearView at highest noise reduction level for thin (0.625 mm) reconstruction slices in MITA body and ACR head phantoms for low contrast objects with different contrasts.
ClearView are not intended to be used in CCT and Pilot.

Device Description:

ClearView reconstruction technology may enable reduction in pixel noise standard deviation and improvement in low contrast resolution. ClearView reconstruction algorithm may allow for reduced mAs in the acquisition of image, thereby it can reduce the dose required.
In clinical practice, the use of ClearView reconstruction may reduce CT patient dose depending on the clinical task, patient size, and clinical practice. A consultation with a radiologist and physicist should be made to determine the appropriate dose to obtain diagnostic image quality for the particular clinical task.
As a reconstruction option, ClearView can be selected before scanning or after scanning. There are 9 ClearView Levels from 10% to 90%. Users can select t.the level of ClearView that is appropriate for the clinical task being performed.
According to the comparison based on the requirements of 21 CFR 807.87, we stated that ClearView reconstruction software is substantially equivalent to the FBP of NeuViz 64 Multi-Slice CT Scanner System.

ClearView is a moderate concern device.

Predicated Devices:

NeuViz 64 Multi-Slice CT Scanner System(K121792).

Statement of Substantial Equivalence:

ClearView is a CT reconstruction technology, which is of comparable type and substantially equivalent to the filter back-projection (FBP) that complies with the same or equivalent standards and has the same intended uses. The end user can choose to apply either
ClearView or the filter back-projection (FBP) to the acquired raw data within the image reconstruction module of the NeuViz 64 Multi-Slice CT Scanner System(K121792).
Depending on the clinical task, patient size, anatomical location, and clinical practice, the use of ClearView can help to reduce radiation dose while maintaining Pixel noise, low contrast detectability and high contrast resolution.
According to the comparison based on the requirements of 21 CFR 807.87, we stated

that ClearView reconstruction software is substantially equivalent to the FBP of NeuViz 64 Multi-Slice CT Scanner System.