



Food and Drug Administration
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Silver Spring, MD 20993-0002

NEUSOFT MEDICAL SYSTEMS CO., LTD.
% Tian Yuehui
Q&R Manager
No. 16, Shiji Road, Hunnan Industrial Area
Shenyang, Liaoning 110179
P.R. CHINA

November 2, 2015

Re: K151403
Trade/Device Name: NeuSight PET/CT 64, NeuSight PET/CT 16
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS, JAK
Dated: September 24, 2015
Received: September 30, 2015

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 (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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style and is positioned over a faint, large watermark of the FDA logo.

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)

K151403

Device Name

NeuSight PET/CT 64,NeuSight PET/CT 16

Indications for Use (Describe)

The NeuSight PET/CT Scanner System can be used for the functional and anatomical imaging of human bodies and organs. The device is intended for whole body or regional tumor examination, cardiac examination and head examination. The device can assist in radiotherapy planning and be used as a stand-alone head and whole body multislice computed tomography (CT) diagnostic imaging system. Trained doctors can read useful diagnostic information from the image generated.

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

K151403

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: NeuSight PET/CT 64, NeuSight PET/CT 16

Common Name: Positron Emission Tomography (PET) and Computed Tomography (CT) System

CFR Section: 21 CFR 892.1200 and 21 CFR 892.1750

Classification Name: Emission computed tomography system
Computed tomography x-ray system

Product Code: KPS/JAK

Classification: Class II

Performance Standard: 21 CFR Subchapter J, Federal Diagnostic X-ray Equipment Standard

Manufacturer: Neusoft Medical Systems Co., Ltd.
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Summary prepared :September 15, 2015

Safety and Effectiveness information

Indications for use:

The NeuSight PET/CT Scanner System can be used for the functional and anatomical imaging of human bodies and organs. The device is intended for whole body or regional tumor examination, cardiac examination and head examination. The device can assist in radiotherapy planning and be used as a stand-alone head and whole body multislice computed tomography (CT) diagnostic imaging system. Trained doctors can read useful diagnostic information from the image generated.

Device Description:

The NeuSight PET/CT Scanner System is an integrated multi-slice Computed Tomography and Positron Emission Tomography scanner. It uses CT images to correct for non-uniform attenuation of the PET images and it uses integrated CT and PET images to localize emission activity in the patient anatomy. NeuSight System has capabilities for imaging all available PET tracers and CT contrast agents and can provide inherently registered anatomical and functional information via an integrated graphical user interface. The product provide some reconstruct methods, such as FBP、3DRP、OSEM、ClearView (cleared in K133373) , and some advance algorithms based on OSEM. These advance algorithms can improve the image quality.

The NeuSight PET/CT Scanner System consists of two variants:

- NeuSight PET/CT 64
- NeuSight PET/CT 16

NeuSight PET/CT 16 is designed based on NeuSight PET/CT 64 and has the same hardware configuration with NeuSight PET/CT 64. Their hardware of CT part is the same as NeuViz64 (K121792). In the performance parameters, NeuSight PET/CT 16 only limits the optional scope of partial scan parameters by software in order to different from NeuSight PET/CT 64. There's no essential technological difference between the two types of PET/CT and the safety and effectiveness of these products could be ensured through verification, validation and difference assessment.

Predicated Device:

GE Discover VCT System(K050559)

Reference Devices

NeuViz 64 CT system (K121792).
NSP-P8 PET Scanner(K090178)

Statement of Substantial Equivalence:

The NeuSight PET/CT System have the same indications for use as the GE Discovery VCT System (K050559). The statement of indications for use is shown below:

Both systems are intended to be used for whole body, multi-slice, positron emission tomography diagnostic imaging, and both systems are intended to be used to image individual patients in a controlled medical facility, such as a hospital, medical center, or mobile medical unit environment.

Both systems can be used for the same population: the patient who needs imaging the distribution of radiopharmaceuticals in the body for the assessment of metabolic (molecular) and physiologic functions.

The NeuSight PET/CT System is similar to "GE Discovery VCT System" (K050559) in the following aspects of design:

PET:

1. Detector crystal type is BGO.
2. Digital detect event position and timing information
3. CT attenuation correction
4. Calibration source is 1 rod source
5. Automatic radiation sources system

CT:

1. Detector/Tube system that can rotate continuously. The Tube emits X-ray beam of fan shape, detector system with multiple channels;
2. Low voltage slip ring and On-Board HV Generator.

PET/CT:

1. Transaxial FOV is 700mm
2. Gantry is air cooling
3. Parallel data acquisition, simultaneous scan and image reconstruction;
4. Patient Couch that can be elevated or lowered (includes a cradle that can be moved horizontally);
5. Also have Static/Dynamic/Gated/WholeBody scan mode.
6. Computerized control of scan and other operations;
7. Computerized image reconstruction and post processing;
8. Digitalized display, storage and output of data/image.

There are some slight differences in PET Detector System between the NeuSight PET/CT System and GE Discovery VCT System” (K050559). A complete comparison table is included in this submission. See below for a brief summary of differences.

Item	NeuSight PET/CT 64	NeuSight PET/CT 16	GE discovery vct (K050559)
Number of detector ring	33	33	24
Number of PMTs	576	576	280 quad PMTs
Number of BLOCK	144	144	(6*8)280
Axial sampling interval	2.516mm	2.516mm	3.27mm

NeuSight PET/CT System does not have significant differences in technological characteristics when compared to the predicate device GE Discovery VCT System. The Indication for Use, operating principle, and the scientific technology are similar. Therefore, we believe that NeuSight PET/CT System is substantially equivalent to the predicate device.

Safety and Effectiveness:

The safety and effectiveness of the NeuSight PET/CT Scanner System was assured by adherence to Good Manufacturing Practices(GMP) 21CFR 820 and to International Standards ISO 13485:2003. These devices are 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: 2008, 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: 2010, 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 60601-2-44:2009, 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
- IEC 62304:2006, Medical device software - Software life-cycle processes
- AAMI ANSI IEC 62366:2007/(R)2013, 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 NU2:2012, Performance Measurements of Positron Emission Tomographs
- NEMA PS 3.1 - 3.20: 2011, Digital Imaging and Communications in Medicine (DICOM)
- 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 if demonstrated via testing. 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) are performed. 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:

Sample clinical images were provided within the submission. The image quality has been evaluated in bind state by a certified radiologist.

Conclusions:

According to the comparison based on the requirements of 21.CFR 807.87, We state that the candidate device and the predicate device are substantially equivalent.