K080927



## 510(k) SUMMARY SAFETY AND EFFECTIVENESS

APR 11 2008

Submitted By:

Philips Medical Systems (Cleveland), Inc.
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| | | |
|---|---|---|
| B. | Device Trade Name: | BrightView™ VCT Imaging System |
| | Common Name: | Single Photon Emission Computed Tomography |
| | Classification Name: | Emission Computed Tomography System |
| | Device Class: | 21CFR 892.1200, Class II |
| | Product Code: | 90 KPS |
| C. | Date prepared: | March 19, 2008 |
| D. | Predicate Devices: | BrightView™ Gamma Camera System (K062298)<br>GE 4 Option for Dual-Head Variable Angle Gamma Camera (K052434) |

E. Intended Use:

BrightView™ VCT is a gamma camera for Single Photon Emission Computed Tomography (SPECT) and integrates with an attenuation device consisting of flat panel x-ray imaging components. BrightView VCT produces non-attenuation corrected SPECT images and attenuation corrected SPECT images with x-ray transmission data that may also be used for scatter correction. The nuclear medicine images and the VCT images may be registered and displayed in a fused format (overlaid in the same orientation) to provide anatomical localization of the nuclear medicine data. The BrightView VCT Imaging System should only be used by trained healthcare professionals.

F. Device Description:

BrightView VCT is a gamma camera for Single Photon Emission Computed Tomography (SPECT) and integrates with an attenuation device consisting of flat panel x-ray imaging components. BrightView VCT is defined as a low dose, high resolution SPECT/CT system with CT-like image quality used to perform attenuation correction and localization. The overall system includes the SPECT gantry, patient table, detectors for emission, flat panel x-ray detector for attenuation correction and localization, acquisition system, processing workstation, image processing/analysis and fusion software, and all other accessories required for the functionality of the system.

The BrightView VCT is designed to provide extended imaging functionality relative to a ring style gantry. It is designed for single or dual detector nuclear imaging accommodating a broad range of emission computed tomography (ECT) studies. The device includes the gantry frame, display panel, two detectors, a collimator storage unit, an acquisition computer unit (with an optional customer desk), a patient imaging table (includes pallet catcher), and a hand controller. The patient imaging table (pallet) is mechanized for patient loading access and for movement during imaging studies. The table may be removed by the operator for imaging of patients in wheelchairs, beds, or gurneys. The pallet includes removable arm, leg/knee, shoulder and headrest supports for patient positioning during studies that require

support. The flat panel x-ray detector can be folded into the gantry to accommodate collimator exchange or bed imaging.

The BrightView VCT is designed to allow acquisition of a broad range of imaging studies using single or dual detectors. When using either a single detector or dual detectors placed in a relative 90-degree or relative 180-degree positions (as study appropriate), BrightView VCT can be used to perform static, dynamic, gated, total body, circular-orbit and non-circular orbit SPECT studies, gated SPECT (circular and non-circular) studies. A flat panel x-ray detector and x-ray tube are mounted to the SPECT gantry to provide attenuation correction and localization capability.

G. Technological Comparison:

The BrightView VCT, the BrightView system (K062298) and GE Hawkeye Infinia (K052434) predicate devices have similar intended use and indications for use. The SPECT portion of the BrightView VCT and the predicate BrightView SPECT are technologically equivalent. The BrightView VCT and the predicate BrightView have similar main mechanical and electrical components. All the SPECT features provided on the BrightView SPECT system are provided on the BrightView VCT. New features include:

- A flat panel detector, x-ray tube and generator for volumetric CT transmission imaging for attenuation correction and localization.
- Change to the BrightView gantry to accommodate mounting of the x-ray imaging components
- Acquisition software for attenuation correction and localization
- Patient table to support 500 lb. load (227 kg)

As stated above the BrightView VCT Gamma Camera System offers the following new features: attenuation correction and localization. The predicate Hawkeye Infinia offers similar SPECT features as well as attenuation correction and localization. The Hawkeye Infinia uses a dental x-ray tube with CT style detectors in a separate plane from the SPECT detectors. The BrightView VCT SPECT and X-ray detectors share a common imaging plane. The BrightView VCT and the Hawkeye Infinia have the x-ray components mounted to the SPECT gantry. The Hawkeye Infinia has a slip ring gantry while the BrightView VCT has a 9-axis ring gantry to provide similar capabilities.

H. Conclusion:

The BrightView VCT is substantially equivalent to the predicate devices BrightView (K062298) and GE Hawkeye Infinia (K052434) based upon identical indications for use, technological comparison and overall system performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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APR 11 2008

Re: K080927
Trade/Device Name: BrightView VCT Imaging System
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: March 31, 2008
Received: April 2, 2008

Dear Mr. Christensen:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

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|---|---|---|
| 21 CFR 876.xxxx | (Gastroenterology/Renal/Urology) | 240-276-0115 |
| 21 CFR 884.xxxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 892.xxxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K080927

Device Name: BrightView VCT Imaging System

Indications For Use:

BrightView VCT is a gamma camera for Single Photon Emission Computed Tomography (SPECT) and integrates with an attenuation device consisting of flat panel x-ray imaging components. BrightView VCT produces non-attenuation corrected SPECT images and attenuation corrected SPECT images with x-ray transmission data that may also be used for scatter correction. The nuclear medicine images and the VCT images may be registered and displayed in a fused format (overlaid in the same orientation) to provide anatomical localization of the nuclear medicine data. The BrightView VCT Imaging System should only be used by trained healthcare professionals.

Prescription Use __X___ (Part 21 CFR 801 Subpart D) OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K080927