



Food and Drug Administration
10903 New Hampshire Avenue
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DDD-Diagnostic A/S
% Mr. Niels Sørensen
RA & Product Engineer
Dr. Neergaards Vej 5E
Horsholm, 2970
DENMARK

October 20, 2016

Re: K161674
Trade/Device Name: QuantumCam 9SYS2070-B02
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: August 9, 2016
Received: June 16, 2016

Dear Mr. Sørensen:

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 over a large, semi-transparent 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)

K161674

Device Name

QuantumCam, 9SYS2070-B02

Indications for Use (Describe)

The QuantumCam is a gamma camera system designed to acquire data for whole body static, gated or dynamic and multi-slice images. The system is intended for use as diagnostic imaging device. When used with appropriate radio pharmaceuticals, images are produced representing the internal distribution of radioactivity in head or body. The system allows you to acquire data for high resolution three dimensional, static, gated or dynamic images of biochemical and metabolic processes using Tc-99m, TI-201, I-123, I-131, In-111, Ga-67, Co-57.

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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5. 510(k) Summary or 510(k) Statement

5.1 510(k) Summary

Ref. to 21 CFR 807.92

- 1 Submitted by: DDD-Diagnostic A/S
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Preparation date: 02 May 2016
- 2 Device Trade Name: QuantumCam (Commercial name) 9SYS2070-B02
(BodyMD is the development name)

Common Name: Gamma Camera System

Classification name: Emission computed tomography system
- 3 Predicate Device: QuantumCam 9SYS2070-A01,
DDD-Diagnostic A/S

510(k) Number: K140206
- 4 Device description: The QuantumCam is a general purpose dual detector gamma camera system comprised of a mechanical gantry allowing the Detectors to be positioned and moved in close proximity to the patient for scanning. The Gantry provides for positioning of the detectors in location(s) suitable for patient to be brought in position for tomographic, whole body scanning as well as planar scanning in sitting or standing position.

- Functional description: The Detectors are standard NaI (Sodium Iodide) / Photomultiplier based scintillation detectors designed following the Anger Camera principles first described by Hal Oscar Anger. This detector technology has been used effectively in Nuclear Medicine for decades. The Detectors are equipped with standard Collimators following the principles known to the industry and this submission is specific about the HEGP collimator. The image data from the detectors are collected by hardware in the detector and the data acquisition is controlled by software running on a standard personal computer with a suitable operating system. The data may subsequently be transferred to a Nuclear Medicine Workstation for processing and interpretation. This Workstation is not part of the QuantumCam system.
- 5 Intended use: The intended use of the QuantumCam gamma camera system is to perform general nuclear medicine imaging procedures. This is intended to be accomplished by imaging the distribution of a radiopharmaceutical within the human body. Gamma rays emitted from the radiopharmaceutical are detected by the gamma camera system and formed into images characterizing and showing the state of organs or structures in the form of functional images. When QuantumCam is connected to a nuclear medicine workstation, these images can be used in concert with other clinical data to assist in making clinical diagnoses by authorized medical personnel.
- Indications for use.
The QuantumCam is a gamma camera system designed to acquire data for whole body static, gated or dynamic and multi-slice images. The system is intended for use as diagnostic imaging device. When used with appropriate radio pharmaceuticals, images are produced representing the internal distribution of radioactivity in head or body. The system allows you to acquire data for high resolution three dimensional, static, gated or dynamic images of biochemical and metabolic processes using Tc-99m, Tl-201, I-123, I-131, In-111, Ga-67, Co-57.
- 6 a Summary of technological characteristics: The submitted device has the same technological and functional characteristics as the predicate device. However the energy range is expanded for the submitted device:

	Submitted device: QuantumCam, 9SYS2070-B02	Predicate device: QuantumCam, 9SYS2070-A01
Design:	The QuantumCam is an open gantry design supported on an open base frame. The complete system is comprised of: a gantry base, detector tower, detector gear box and two imaging detectors, collimator cart, PC, and electronics including a main PSU.	The QuantumCam is an open gantry design supported on an open base frame. The complete system is comprised of: a gantry base, detector tower, detector gear box and two imaging detectors, collimator cart, PC, and electronics including a main PSU.
Material:	The QuantumCam employs detector of scintillation crystals in a traditional Anger design. The gantry and patient table employs steel and anodized aluminum, steel plate and aluminum covers.	The QuantumCam employs detector of scintillation crystals in a traditional Anger design. The gantry and patient table employs steel and anodized aluminum, steel plate and aluminum covers.
Energy source:	Mains supply. 200VAC – 240VAC	Mains supply. 200VAC – 240VAC
Detector:	The QuantumCam has two separate detectors. Each detector casting is supported by means of a U-shaped detector arm in a balanced design enabling manual tilt of the detector. The complete detector is comprised of: a detector casting, a NaI detector crystal, PM tubes, collimators and electronics for data processing.	The QuantumCam has two separate detectors. Each detector casting is supported by means of a U-shaped detector arm in a balanced design enabling manual tilt of the detector. The complete detector is comprised of: a detector casting, a NaI detector crystal, PM tubes, collimators and electronics for data processing.
Energy range:	40 – 400 keV	40 – 300 keV

Software:	<p>The QuantumCam acquisition station is based on a PC architecture with Windows 7 64bit operating system and Microsoft SQL for database handling. A dedicated S/W package for Graphic User Interface (GUI) - S/W package for acquisition setup and gantry/detector motion control. The package also includes means for data transmission via an external network.</p>	<p>The QuantumCam acquisition station is based on a PC architecture with Windows 7 64bit operating system and Microsoft SQL for database handling. A dedicated S/W package for Graphic User Interface (GUI) - S/W package for acquisition setup and gantry/detector motion control. The package also includes means for data transmission via an external network.</p>
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6 b Description of how the non clinical test results have been collected:

Non clinical data has been obtained according to DDD quality system procedures. The HEGP Collimator is a late addition to the range of collimators for QuantumCam and verification is done according to standards as listed below, conducted and reported by qualified experts:

Specifications:	<p>Collimator hole: Shape = HEX Size = 3.0 mm Septa = 1,75 mm Length = 43 mm</p>	<p>Measured and compared to Unicorn drawings.</p>
	<p>Sensitivity: 183 cpm/uCi</p>	<p>NEMA test on a QuantumCam system.</p>
	<p>Spatial Resolution @ 10cm, HEGP collimator: < 16.5 mm</p>	<p>NEMA test on a QuantumCam system.</p>
	<p>Septal Penetration: 39,8 %</p>	<p>NEMA test on a QuantumCam system. The official specification is based on septa thickness and is calculated based on the absorption characteristics of lead (4,8%).</p>

<p>Detector shielding: Li = 6,4% LFI = 1,4% LSi = 20%</p>	<p>The QuantumCam detector was mounted with a High Energy General Purpose collimator (HEGP). A I-131 source (364 keV) in source holder. NEMA test on a QuantumCam system.</p>
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Rationale for substantial equivalence: Energy Range is expanded for the submitted device to be able to use high energy isotopes such as I-131. For this purpose a HEGP collimator is added to the range of existing collimators for QuantumCam. They all have similar characteristics and the choice of which collimator to use is the users, based on guidelines from professional societies. Adding the HEGP collimator still fulfill the intended use of the QuantumCam system.

The two devices are therefore considered substantial equivalent.

Conclusion: The submitted device has been evaluated for effectiveness, electrical and mechanical safety, and has been found in compliance with applicable medical device standards, as referred to in Appendix 2. Based on this DDD considers the submitted device, QuantumCam (expanded energy range) 9SYS2070-B02 to be substantially equivalent in terms of safety and effectiveness to the predicate device, QuantumCam 9SYS2070-A01.