K051460

JUN 15 2005

B ADMINISTRATIVE INFORMATION

B-1 Summary of Safety and Effectiveness Statement

B-1-1 Ref. CFR 807.92

1	Submitted by:	3D, Danish Diagnostic Development A/S Dr. Neergaardsvej 5F 2970 Horsholm, Denmark Tel: + 45 45 768888 Fax: + 45 45 164659
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	Preparation date:	2 March 2005
2	Device Trade Name:	c.cam-AC
	Common Name:	Attenuation Correction Device
	Classification name:	Emission computed tomography system
3	Predicate Device: 510(K) Number:	1. CardioMD-AC. 3D, Danish Diagnostic Development A/S. K040616.
		2. E.cam-AC. Siemens Medical Solutions USA, Inc. K963983. Refer to section C3 Comparison of the New and Predicate Device, subpart; **Radioactive source,** and to section C3 Comparison of the New and Predicate Device, subpart; **Performance.**
4	Device description:	The c.cam-AC is an attenuation correction device, which will be marketed as an optional device for the c.cam gamma camera.
	Functional description:	C.cam gamma camera is a dual detector system and the attenuation correction device (two units) will be mounted opposite of the two detectors, one device on each detector. The attenuation correction device is formed as two housings each containing 14 line sources in fixed positions, shutter and all shutter control. The following described functions are performed on both detectors simultaneously. When the scanning is initiated the emission image and the transmission images are acquired sequentially. When the emission image has been acquired, a shutter, common for all sources, located in the device housing will open for exposure from 14 line sources (max. 20 mCi each ^{153} Gd with a total

		of max. 96 mCi). A collimated beam of gamma ray photons is focused on the opposite detector field of view to create the transmission images of the patient placed in the field of view of the detector. Having acquired both emission and transmission images, the data for emission, transmission, emission scatter and transmission scatter are stored in one dataset. A scaled version of the blank transmission scan is stored in another dataset. The complete study can be export via DICOM to the OEM customer provided processing station for later processing and reviewing.

5	Intended use:	Attenuation correction is a method where the emission images acquired during SPECT acquisitions are compensated for attenuation within the patient. The purpose of attenuation correction is to compensate for varying attenuation of gamma rays in the body. The intended use of the c.cam Attenuation Correction option is to provide the customer with means to measure the attenuation of gamma rays within the body of a patient, when using a c.cam gamma camera system for SPECT studies, and to map the measured attenuation into images that can be used to compensate emission images for the attenuation. The c.cam-AC includes additional acquisition of data for scatter correction of these images.

6 a	Summary of technological characteristics:	The device has the same technological and functional characteristics as the predicate device. However the design of the submitted device is different on the following points: 1. Manually positioning of the device housing. 2. The use of 14 fixed positioned sources.		
		Submitted device: c.cam-AC	**Predicate device: CardioMD-AC**	**Predicate device: e.cam-AC (equivalence claimed to radioactive source only)**
	Design:	The submitted attenuation correction device is formed as a single housing containing 14 line sources in fixed positions, shutter and all shutter control. The device is secured to the side of the detector casting by means of a bracket. The bracket is designed for manual positioning of the device housing to enable patient access to the system.	The predicate attenuation correction device is formed as a single housing containing all motion control, electronics and motors including the scanning line source. The device is secured to the side of the detector casting by means of a bracket that enables the device housing to slide in and out.	

		In operation the device housing is manually positioned opposite to the detector. When not in use the device housing can manually be rotated to its park position enabling access for patient loading and un-loading.	In operation the device housing is positioned opposite to the detector (motorized motion). When not in use the device housing can slide to its park position enabling access for patient loading and un-loading.	
	Radioactive source:	The submitted device utilises 14 fixed positioned line sources exposing the complete detector field of view. Each source is collimated to minimize exposure to the surroundings and the patient exposure is controlled by an electrical controlled shutter common for all 14 sources.	The predicate device utilises one collimated line sources exposing by scanning over the detector field of view. The shutter controlling the patient exposure is an integrated part of the source holder.	The predicate device utilises 14 fixed positioned line sources exposing the complete detector field of view. Each source is collimated to minimize exposure to the surroundings and the patient exposure is controlled by an electrical controlled shutter common for all 14 sources. The two devices utilises the same line sources type from the same supplier in the same housing.
	Material:	Anodized aluminium plates, lead and lead alloy shielding. Painted aluminium plate covers.	Anodized aluminium plates, lead and lead-bronze alloy shielding. Painted aluminium plate covers.	
	Energy source:	Powered from an isolated power outlet on the mains supply. 120 VAC	Powered from an isolated power outlet on the mains supply. 120 VAC	
6 b	Description of how the non clinical test results have been collected.	Clinical data has been collected by acquiring Myocardial Perfusion stress studies on a Siemens e.cam system. Refer to section C-4-2 *Phantom Data Images* and to C-6-1 A brief description of how the clinical data has been obtained.		
	Radiation Leakage	Exposure from surface of housing, shutter closed: < 0.2 mR/hr @ 100cm. Exposure during scan, at 30 cm, shutter opened: < 10 mR/hr @ 30cm.		

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 15 2005

Danish Diagnostic Development A/S
% Mr. Jeffrey D. Rongero
Project Engineer
Underwriters Laboratories, Inc.
12 Laboratory Drive, P.O. Box 13995
Research Triangle Park, NC 27709-3995

Re: K051460
Trade/Device Name: c.cam-AC
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: April 21, 2005
Received: June 3, 2005

Dear Mr. Rongero:

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 (Premarket Approval), 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 Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

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" (21 CFR 807.97). 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 (301) 443-6597 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

B-2 FDA Indications for Use Form

Indications for Use Form

510(k) Number (if known): ~~Not Known~~ K051460

Device Name: c.cam - AC

Indications For Use:

Attenuation correction is a method where the emission images acquired during SPECT acquisitions are compensated for attenuation within the patient. The purpose of attenuation correction is to compensate for varying attenuation of gamma rays in the body.

The intended use of the c.cam Attenuation Correction option is to provide the customer with means to measure the attenuation of gamma rays within the body of a patient, when using a c.cam gamma camera system for SPECT studies, and to map the measured attenuation into images that can be used to compensate emission images for the attenuation. The c.cam-AC includes additional acquisition of data for scatter correction of these images.

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 Device Evaluation (ODE)

David B. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K051460

Page __ of __

(Posted November 13, 2003)