Diagnostic

Danish Diagnostic Development A/S

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JUL 11 2008

June 10, 2008

CapIMAGE Gamma Camera System

510(k) Summary" as required by section 807.92(c).

Assigned 510(K) number: K081829

1. Submitter Information.

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Prepared: June 10, 2008

2. Device Information.

Device:	Device Trade Name:	CapIMAGE
	Device Model number:	9THY1660
	Common Name:	Gamma Camera
	Classification name:	Scintillation Gamma Camera
	Classification:	Class I. 892.1100

3. Predicate Device Information.

Predicate device:	Device Trade Name:	CardioMD (initially Cardiocam).
	Product code:	90-KPS
	510(K):	K011611

4. Device Description.

The CapIMAGE is a mobile Small Field of View (SFOV) gamma camera system utilizing a scintillation detector to detect gamma rays. The CapIMAGE is designed to be manually transported and deployed for scanning of patients in laying, sitting or standing positions. The system can operate powered from mains or from the internal battery source for at least 60 min.

Functional.

Analog signals from the photo multiplier tubes are summed into position and energy signals and sent to the camera console digitization and correction. The corrected data are hereafter send to a laptop PC located on top of the camera console, acting as a combined control and user interface to the system. Detector positioning is done using the persistence display mode on the PC, showing radioactive emission from the patient. The vertical detector positioning is motorised, all other positioning is done manually, using controls on the detector, including acquisition start and stop. The PC user interface (UI) enables the user to enter image acquisition parameters and to start and stop image acquisition. Following acquisition, images can be reviewed on the PC, processed and/or transferred to a peripheral device using DICOM

Performance characteristics.

Energy range:	59kev – 167kev
Detector UFOV:	Ø 210 mm (8.3")
Intrinsic Spatial Res.:	≤ ± 3.7mm @ UFOV / FWHM
Energy Resolution:	≤ 9.4% @ Tc-99m
Spatial Linearity:	<± 0.5mm @ UFOV
Flood Field Uniformity:	<± 2.7% @ UFOV Intrinsic
Intrinsic Uniformity, UFOV, Differential	< 1.5%
Count rate Performance:	>180k cps @ 20% loss
Spatial Resolution, FWHM, LEGP Tc-99m.	< 9.4mm

5. Statement of Intended Use.

The CapIMAGE Gamma Camera System is intended to produce planar images depicting the anatomical distributions of single photon emitting radioisotopes in the human body within the energy range of 59kev to 167kev. The system provides software applications for processing, analyzing, and displaying medical images for interpretation by medical personnel.

The CapIMAGE Gamma Camera System is intended for examination (and diagnosis) of disorders and diseases in the thyroid gland, the heart and other small organs. The device is not interpretative. Data from the device are interpreted by medical personnel who, based on these, make the clinical diagnosis.

The difference between the CapIMAGE and the CardioMD intended use is that the CardioMD includes cardiac SPECT, whereas the intended use of CapIMAGE includes planer cardiac imaging and planar imaging of other organs enabled by its single detector. CapIMAGE are considered to be substantial equivalent to the CardioMD device since they both perform planar imaging. Also, labelling of the CapIMAGE is substantially equivalent to the predicate device, providing the adequate directions for use and warnings, needed to ensure the safe effective use of the device.

6. Technological Characteristics.

Design:

The submitted device is a mobile gantry design supported on wheels. It includes a detector, supported by a horizontal arm, a laptop PC for image acquisition and processing and electronics. The submitted device has the same technological and functional characteristics as the predicate device. Both systems are gamma camera systems with detector technology based on the Anger principle and designed to perform acquisition of diagnostic images. However, the submitted device differs from the predicate device on the following:

- The CapIMAGE is a planar system (no automatic motions), whereas the CardioMD is a tomography SPECT system.
- The CapIMAGE is a mobile system whereas the CardioMD is designed for permanent installation.
- The CapIMAGE is a single detector system whereas the CardioMD is a dual detector system.
- The CapIMAGE system includes no collision detection system whereas the CardioMD is provided with collision sensors on the detector and collimators to protect the patient during automatic motions.

Material:

Both the submitted and the predicate device utilize similar material including iron base structure, iron and aluminium plates and casted copper/zinc/lead structures where shielding is necessary.

Energy source:

Both the submitted and the predicate device are supplied from mains supply. However, the submitted device includes battery backup power. The main purpose of this is to maintain power on the detector, for detector performance stability during manoeuvring.

Patient Support:

Regarding patient support, the submitted device differs from the predicate device since the CapIMAGE system does not provide any support for the patient, whereas the predicate device supports the patient in a lying position during scanning.

Detector:

The detector for the submitted and predicate device is mounted in a casted housing and both include a NaI crystal, photo multiplier tubes and electronics for analog and digital signal processing. Both devices utilize the same technology based on the Anger principle. However, the submitted device detector differs from the predicate device on the following:

- The CapIMAGE detector has a circular field of view, whereas the CardioMD has a rectangular field of view.
- The CapIMAGE detector does not include any electronics for digitalisation and correction (since this is located in the gantry and PC), whereas the CardioMD detector includes means for complete detector corrections within the detector.
- The CapIMAGE product includes only one detector, whereas the CardioMD includes two detectors in the same casting.

Software:
The CapIMAGE is based on a Windows Vista PC platform, supporting a dedicated acquisition software package. The package consists of processing software, a graphical user interface including a patient database, and a DICOM interface for data transmission to external processing devices. The software does not include control for any automated detector or system motions. In addition to processing software, graphical UI, patient database and a DICOM interface, the predicate device includes software for setup and control of automated gantry motion during SPECT.

Indication for use:
The CapIMAGE Gamma Camera System is intended to produce planar images depicting the anatomical distributions of single photon emitting radioisotopes in the human body within the energy range of 59kev to 167kev. The system provides software applications for processing, analyzing, and displaying medical images for interpretation by medical personnel. Both the submitted and the predicate device are designed for imaging the anatomical distributions of single photon emitting radioisotopes within the human body for interpretation by medical personnel. The predicate device is further designed for multi-slice imaging (SPECT).

Performance:

Detector Specifications: The submitted and the predicate device have basically the same performance except difference in the field of view size.

Gantry Specifications: The major difference between the submitted and the predicate device is that the predicate device is designed for both planar and SPECT imaging whereas CapIMAGE are designed for planar imaging only. This allows the CapIMAGE gantry to be much simpler and lighter enabling manual transportation of the device.

7. Non-clinical Performance Data.

The CapIMAGE performance characteristics have been tested in accordance with applicable standards for medical device during which the CapIMAGE has shown full compliance.

Safety and effectiveness.	Compliance to all relevant parts of the UL 60601-1, IEC601-1, IEC601-1-1 and IEC601-1-2 standards.
Performance specifications.	Compliance to all relevant parts of the NEMA NU 1- 2001 standard.

Based on these data it is concluded that the CapIMAGE provides effective results equivalent to those from the predicate device, the CardioMD.

8. Clinical Performance Data.

None.

9. Conclusion.

The main intention of the CapIMAGE is to produce planar images of radioisotopes within the human body. As such the CapIMAGE can be concluded to be substantial equivalent to the predicate device. Data presented in this 510(k) submission demonstrate that the CapIMAGE system is as safe and effective and performs in a manner equivalent to the predicate device.

10. Any Other Information.

None.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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JUL 11 2008

Danish Diagnostic Development A/S
% Mr. Casey Conry
Senior Project Manager
Underwriters Laboratories, Inc.
1285 Walt Whitman Road
MELVILLE NY 11747

Re: K081829
Trade/Device Name: CapIMAGE
Regulation Number: 21 CFR 892.1100
Regulation Name: Scintillation (gamma) camera
Regulatory Class: I
Product Code: IYX
Dated: June 20, 2008
Received: June 27, 2008

Dear Mr. Conry:

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.

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): K081829

Device Name: **CapIMAGE.**

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Prescription Use ___X___ (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)

(Posted November 13, 2003)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K081829