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
	Contact person:	Niels Sorensen Tel: + 45 45 768888 Fax: + 45 45 164659 E-mail: nes@3dnm.dk
	Preparation date:	29 April 2003
2	Device Trade Name:	Virgo
	Common Name:	Gamma Camera System
	Classification name:	Emission computed tomography system
3	Predicate Device:	3D, Danish Diagnostic Development A/S, CardioMD
	510(K) Number:	K011611
		3D, Danish Diagnostic Development A/S, Unicorn (K001888) Refer to section C3 Comparison of the New and Predicate Device, subpart; **Indications for use statement.**
4	Device description:	The Virgo system design comprises a gantry supporting a fixed 90 degree dual head detector and a patient chair. The Virgo system is operated through interaction with a graphical user interface situated on the acquisition PC and a dedicated Virgo hand controller.
	Functional description:	The patient ascends the chair. When the acquisition setup has been completed on the acquisition PC, preprogrammed motions declines the chair and patient to slanted position and the detectors brought to a predetermined position. When a tomography is acquired, the handset is used to position the detector in close proximity to the patient to enter contour marks to determine the detector orbit for the acquisition. For planar imaging, the handset is used to position the detectors. When the detectors are in position, the acquisition is started. During acquisition, the detector detects gamma photons emitted from the patient. For each photon detected, the detector determines the energy and position (two-dimensional) from where the photon originated within the patient. The detector corrects for uniformity and linearity errors before sending energy and

position data to the acquisition PC. The acquisition PC frames the received data into images. Once the acquisition terminates, the resulting images and data is stored in the acquisition PC database for later reviewing and export via DICOM to the OEM customer provided processing station.

5 Intended use:

Virgo is an emission computed tomography system intended to detect the location and distribution of gamma ray radionuclides in the body and produce cross-sectional images through computer reconstruction of the data. The device includes display equipment, patient and equipment supports, component parts, and accessories.

Virgo is primarily intended for cardiac applications but the Virgo design also supports non-cardiac procedures of the patient's chest region and body extremities.
Virgo supports radionuclides within the energy range of 60 – 170 keV

6 a Summary of technological characteristics:

The device has the same technological and functional characteristics as the predicate device. However, the gantry with patient support device is in design significantly different:

	Submitted device: Virgo	**Predicate device: CardioMD**
Design:	A gantry base on the floor supports a console with electronics and a robotic detector arm. The detector arm serves as detector support in an unbalanced design. Detector motions for positioning the detectors and for orbiting the detectors circularly and non-circularly around the patient is achieved by a combination of: Horizontal translation of the console with detector arm and detector towards the patient. Rotation of the robotic arm with the detector. Rotation of the detector on the robotic arm. Further the gantry base supports a patient chair in which the patient is seated during acquisition and a stand for the acquisition PC.	A gantry base on the floor supports a tower that holds the detector in an unbalanced design. Detector motions for positioning the detectors and for orbiting the detectors circularly and non-circularly around the patient is achieved by a combination of: Horizontal translation of the tower with the detector towards the patient. Vertical translation of the detector. Rotation of the detector on the tower. Further the gantry base supports a table console with electronics that acts as support for a patient table on which the patient is lying during acquisition. The acquisition PC is located on a separate rollable PC cart.
Material:	Painted and cromated iron and aluminum plates and casts. Aluminum plate covers.	Painted and cromated iron and aluminum plates and casts. Aluminum plate covers.

Energy source:	Mains supply. 100 VAC – 240 VAC	Mains supply. 100 VAC – 240 VAC
Patient Support:	The patient support comprises a chair mounted on the gantry base in which the patient is seated supine during acquisition. The chair consists of a back pad and a seat pad mounted onto an S-shaped iron frame. The back pad has a cutout towards the detector to enable close detector proximity to small patients. The chair includes a rotate motion capable of tilting the entire chair with patient between upright position (patient load) and a declined scan position about 20 degrees from horizontal. By manual control, the seat of the chair (with patient) can be moved up and down to position the heart of both tall and short patients within the detector field of view.	The patient support comprises a table mounted on the table console on which the patient is lying horizontally supine or prone during acquisition. The table consists of a thin aluminum plate with a mattress. The aluminum table has a cutout towards the detector to enable close detector proximity to small patients. By manual control, the table can be translated manually to position patient's heart within the detector field of view.
Detector:	The two fixed 90 degrees detector heads are mounted into a single copper/ zinc/lead alloy (UNS designation; C94300) casting covered by aluminum plate covers with collision sensors and pads. Each detector comprises a NaI crystal and 24 3" square photomultiplier tubes and electronics for position determination and correction for uniformity and linearity errors. The detector outputs corrected events as energy and position data embedded in an IEEE 1394 Firewire bus to the connected acquisition PC.	The two fixed 90 degrees detector heads are mounted into a single copper/ zinc/lead alloy (UNS designation; C94300) casting covered by aluminum plate covers with collision sensors and pads. Each detector comprises a NaI crystal and 24 3" square photomultiplier tubes and electronics for position determination and correction for uniformity and linearity errors. The detector outputs corrected events as energy and position data embedded in an IEEE 1394 Firewire bus to the connected acquisition PC.

Software:	The Virgo acquisition station is based on a Windows PC platform running a dedicated acquisition software package. This software is formed by: A graphical user interface package including the patient database and DICOM interface A camera control package designed for the purpose of controlling system setup, gantry/chair motions and image framing.	The CardioMD acquisition station is based on a Windows PC platform running a dedicated acquisition software package. This software is formed by: A graphical user interface package including the patient database and DICOM interface A camera control package designed for the purpose of controlling system setup, gantry/patient table motions and image framing.

6 b	Description of how the non clinical test results have been collected.	In general, all non clinical test results have been collected following documented verification plans. Whenever possible, these plans are following relevant and recognized standards and guidelines like the NEMA Standard NU 1-1994. Below is a list of a subset of the more important specifications with a description of how these test results are collected.
	Intrinsic Spatial Resolution, FWHM, UFOV: ≤± 3.7mm	Test equipment used, test setup and all calculations have all been performed according to the NEMA Standard NU 1-1994.
	Spatial Resolution, FWHM, LEGP collimator @ 10cm, Tc-99m: < 9.2 mm	Test equipment used, test setup and all calculations have all been performed according to the NEMA Standard NU 1-1994. (section 3.5.3)
	Energy Resolution, @Tc-99m: ≤9.4%	Test equipment used, test setup and all calculations have all been performed according to the NEMA Standard NU 1-1994.
	Spatial Linearity, UFOV: < ± 0.5 mm absolute.	Test equipment used, test setup and all calculations have all been performed according to the NEMA Standard NU 1-1994.
	Intrinsic Flood Field Uniformity, UFOV Integral: < ± 2.5 %	Test equipment used, test setup and all calculations have all been performed according to the NEMA Standard NU 1-1994.
	Maximum Count rate: > 180k cps with scatter > 290k cps w/o scatter	Test equipment used, test setup and all calculations have all been performed according to the NEMA Standard NU 1-1994.
	Count rate @ 20 % loss. > 225k cps	Test equipment used, test setup and all calculations have all been performed according to the NEMA Standard NU 1-1994.
	Detector Background Sensitivity, @180 °, 140 keV: < 2.0 %	The Virgo detector was mounted with a Low Energy General Purpose collimator (LEGP). A 140 keV source in source holder (NEMA standard fig. 2-4) was placed 10 cm in front of the collimator. With 20% symmetric energy window setting the count rate was verified (less than 10 k cps). Moving the source 360 ° around the Detector in X- and Y direction the position of the maximum count rate was found. The maximum % was calculated according to NEMA Standard NU 1-1994.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 0 2003

Danish Diagnostic Development A/S
% Ms. Susan Gill
Senior Project Engineer
Underwriters Lanoratories, Inc.
12 Laboratory Drive
P.O. Box 13995
Research Triangle Park, NC 27709-3995

Re: K031825
Trade/Device Name: "Virgo" Model 9VIR1200
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: 90 KPS
Dated: June 12, 2003
Received: June 13, 2003

Dear Ms. Gill:

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 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.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

Page 1 of 1

510(k) Number (if known): K031825

Device Name: Virgo

Indications For Use:

Virgo is an emission computed tomography system intended to detect the location and distribution of gamma ray radionuclides in the body and produce cross-sectional images through computer reconstruction of the data. The device includes display equipment, patient and equipment supports, component parts, and accessories.

Virgo is primarily intended for cardiac applications but the Virgo design also supports non-cardiac procedures of the patient's chest region and body extremities. Virgo supports radionuclides within the energy range of 60 – 170 keV

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Lippman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K031825