Spectrica

MAR 2 3 2006

K060486

26 510(k) SUMMARY

As required by 21 CFR 807.92

26.1 Application Identification

Applicant's Name and Address:	Spectrica. 15 Antares Drive, Unit #2, Ottawa, Ontario, Canada K2E 7Y9 Tel: 613-225-5554 Fax: 613-225-3331
Contact Person:	Steve Jude Tel: (613) 225-5554 ext. 307 Fax (613) 225-3331 Email: sjude@spectrica.com
Address of Manufacturing Site:	Same as Applicant's address above
Summary Date:	February 22, 2006

26.2 Device Identification

Device Name:	Cyclone
Trade Name:	maiCAM180
Common Name:	Gamma Camera System
Regulation Name:	Emission Computed Tomography System as per 21 CFR 892.1200

26.3 Type of Submission

Traditional

26.4 Predicate Device

Manufacturer:	3D, Danish Diagnostic Development
Trade Name:	Virgo
510(K) Number:	K031825
Classification Code:	90 KPS

26.5 Device Description

Description: The Cyclone camera is a dedicated Gamma Camera for nuclear cardiology. The intended use of Cyclone is to detect the location and distribution of gamma ray emitting radionuclides in the body and store the image data. This device includes accessories such as signal

analysis and display equipment, patient and equipment supports, radionuclide anatomical markers, component parts, and accessories. Radiopharmaceuticals are administered intravenously. The Cyclone records the distribution of the tracer in vivo. Gamma rays are emitted from the tracer. A collimator is used to accept only the gamma rays with defined orientations, usually parallel for detection. The collimator is actually analogous to a camera lens. The gamma rays admitted into the scintillation camera detector interact with a scintillating crystal, causing a very small flash of light at each point of interaction. The crystal is large, flat and thin (see specifications for size). The pattern of light flashes is detected by photomultiplier tubes that convert the light into electrical signals, each signal proportional to the energy of the gamma ray and also carrying precise positional information. Only gamma rays with the correct energy for the tracer used and with meaningful orientation to the patient are imaged.

The Cyclone camera consists of a base which supports a wall or track that in turn supports and guides a fixed 90 degree dual head around a patient chair. The motions and set-up of the camera can be controlled with the hand control. Detector motions are controlled by software and are initiated by the hand control.

26.6 Intended Use

The Cyclone is an emission computed tomography system intended to detect the location and distribution of gamma ray emitting radionuclides in the body and produce cross-sectional images through computer reconstruction of the data.

The Cyclone intended use is for cardiac applications. The Cyclone supports radionuclides within the energy of 50-200keV.

26.7 Substantial Equivalence Comparison:

Summary: The device has the same technological and functional characteristics as the predicate device. The Cyclone and the predicate device are essentially diagnostic tools with the same indications for use. This comparison shows that no new safety and effectiveness concerns are raised concerning the Cyclone.

Comparison Table:

Feature/Spec	Predicate - Virgo	Cyclone
FDA status	FDA 510k Clearance	n/a
FDA 510k #	K031825	Unknown
Intended Use	The intended use is to detect the location and distribution of gamma ray emitting radionuclides in the body and produce cross-sectional images through computer reconstruction of the data. This device includes accessories such as signal analysis and display equipment, patient and equipment supports, radionuclide anatomical markers, component parts, and accessories.	The intended use is to detect the location and distribution of gamma ray emitting radionuclides in the body and produce cross-sectional images through computer reconstruction of the data. This device includes accessories such as signal analysis and display equipment, patient and equipment supports, radionuclide anatomical markers, component parts, and accessories.
Target Population	The Virgo is primarily intended for cardiac applications in a clinical environment.	Same
Electrical Safety	Device is certified to electrical safety standards by a third party organization prior to use on human patients.	Same
Energy used/delivered	There is no new energy source requirement. The energy requirement is 115 V, 60 Hz (or 240 V, 50 Hz)	Same

Standards met	IEC 601 and UL544	Same
User Instructions	User instructions contain the operating instructions pertinent to this system including safety features, warnings, system calibration, and processing and workstation features and instructions.	Same.
Design	A gantry base on the floor supports a console with electronics and a robotic detector arm. The detector arm serves as a detector support in an unbalanced design.	The gantry base on the floor supports a wall / track that hold the detectors in an unbalanced design.
Material	Painted and cremated iron and aluminum plates and casts.	Painted and cremated iron and aluminum plates.
	Aluminum plate covers.	Sheet metal and plastic covers.
Patient Support	The patient support comprises a chair mounted on the gantry base in which the patient is seated supine during acquisition.	The patient support comprises a chair mounted on the gantry base in which the patient is seated upright during acquisition.
	The chair includes a rotate motion capable of tilting the entire chair with patient between upright position (patient load) and a decline scan position about 20	The chair is capable of moving in the X and Y axis relative to the detector heads while the detector rotate in the Z axis around the patient.

	degree from horizontal.	
	By manual control, the seat of the chair (with patient) can be moved up or down to position the heart of the patient within the detector head.	By manual control, the seat of the chair (with patient) can be moved up or down to position the heart of the patient within the detector head.
Detector Design	The two detector heads are mounted into a single copper / zinc/ lead alloy (UNS) designation;C94300 casting covered by aluminum plate covers with collision sensor pads.	The two detector heads are mounted into a separate lead / aluminum bowl covered by sheet metal covers with collision sensor 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.	Each detector comprises a NaI crystal and 35 2.3" square photomultiplier tubes and electronics for position determination and correction for uniformity and linearity errors.
Warnings	A warning label is applied to all collimators highlighting instructions. Caution and high voltage labels are applied in appropriate areas and as required by electrical standards.	Same

Physical Description:		
1) Field of View	14.6 × 8.4 inches	14.8 x 9.5 inches
2) PMT's	24 tubes per head	35 tubes per head
4) Operator Interface	Hand-control and keyboard used for image acquisition, detector head and gantry control	Same
Performance:		
1) Energy range	60 - 170 keV	50 - 200 keV
2) Count rate	290 Kcps	300 Kcps
3) Energy resolution	≤9.4 % FWHM	9.2 % FWHM
4) Intrinsic uniformity	≤2.5 % integral ≤ 1.5 % differential	≤2.5 % integral ≤ 1.5 % differential
5) Intrinsic spatial resolution	≤3.7 mm FWHM ≤7.6 mm FWTM	≤3.0 mm FWHM ≤6.2 mm FWTM
Acquisition Software:	Segami Mirage Acquisition	Segami Mirage Acquisition

Performance
All tests have been performed based NEMA Standards. NU 1-2001, Performance Measurements of Scintillation Cameras.

26.8 Conclusion

In the opinion of Spectrica, the Cyclone camera is substantially equivalent in terms of safety and effectiveness to the legally marketed Virgo (K031825) system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 3 2006

Mr. Steve Jude
General Manager
Spectrica
15 Antares Drive, #2
Ottawa, Ontario, K2E 7Y9
CANADA

Re: K060486
Trade/Device Name: Cyclone – maiCAM 180
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: February 23, 2006
Received: February 24, 2006

Dear Mr. Jude:

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

11 INDICATION FOR USE – OPTIONAL FORMAT 1-2-96

Indication for Use

510(k) Number (if known): [redacted] K060486

Device Name: Cyclone - maiCAM180

Indication for Use:

The Cyclone is an emission computed tomography system intended to detect the location and distribution of gamma ray emitting radionuclides in the body and produce cross-sectional images through computer reconstruction of the data. The data can then be transmitted to, or retrieved by, existing commercially available image processing software packages and accompanying computer equipment.

The Cyclone intended use is for cardiac applications. The Cyclone supports radionuclides within the energy of 50-200keV.

Prescription Use ✓ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Hoyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060486