K072191

B Administrative Information

OCT 25 2007

B.1 510(k) Summary of Safety and Effectiveness

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The following information is in accordance with 21 CFR 807.92.

B.1.1 Submitted By:

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Date Prepared:	3-August-2007

B.1.2 Device Identification

Trade / Proprietary Name:	ClearVision Nuclear Imaging System
Common Name:	SPECT System
Classification Name:	System, Emission Computed Tomography
21 CFR Number:	892.1200
CDRH Product Code:	90 KPS
Regulatory Device Class:	II
Classification Panel:	Radiology

B.1.3 Predicate Device

Manufacturer:	Digirad Corporation
Trade Name:	Cardius 1 XPO and Cardius 2 XPO SPECT Imaging Systems
510(k) Number:	K070542
CDRH Product Code:	90 KPS

B.1.4 Device Description

The ClearVision Nuclear Medicine Imaging System acquires and processes cardiac data including gated and non-gated Single Photon Emission Computed Tomography (SPECT) studies. After completion of an acquisition, the operator can select the resulting acquisition data file to generate both qualitative and quantitative results for review by a physician. This includes processing using Release 5.6 of Segami Corporation's Mirage processing software that was previously cleared under 510(k) number K043441 dated 13-January-2005.

The acquisition system consists of either a single or dual small field-of-view detectors with each mounted on top of a tower that contains system electronics. To support the acquisition of SPECT data, the patient chair rotates up to 360 degrees in either clockwise or counterclockwise direction.

Prior to a patient scan, the following system features are used to ensure the myocardium is centered within each detector's field of view (FOV):

- Each tower can be moved horizontally along rails mounted to the floor plate.
- The patient chair seat pan can be moved side-to-side.
- Vertical and a horizontal beam lasers are mounted to side of detector.

The ClearVision system's compact footprint and small FOV detector are specifically designed for placement in a facility lacking adequate floor space for a typical nuclear medicine imaging system.

B.1.5 Intended Use

The ClearVision nuclear medicine imaging system is intended for use as a diagnostic imaging device to acquire and process gated and non-gated Single Photon Emission Computed Tomography (SPECT) images.

Used with appropriate radiopharmaceuticals, the ClearVision system produces images that depict the anatomical distribution of radioisotopes within the myocardium.

B.1.6 Substantial Equivalence Comparison

The ClearVision is of a comparable type and substantially equivalent to the Digirad Cardius 1 XPO and Cardius 2 XPO SPECT Imaging Systems (510(k) Number K070542), as both devices are used to acquire gated and non-gated SPECT studies using similar physical characteristics (refer to feature comparison summary table in Section B.1.7). In addition, the detector layout and electronics are identical in both physical and performance characteristics to the detector used on the GVI Medical Devices OnePass Nuclear Imaging System (510(k) K023373).

The primary difference between the ClearVision and the Cardius 1 and 2 XPO Systems is in detector technology and collimation. ClearVision uses traditional Anger technology detectors along with proprietary inverse fan-beam collimators, while the Cardius XPO systems use solid-state detectors and parallel-hole collimators. Refer to Attachment B for detailed description of the inverse fan-beam collimator.

B.1.7 Feature Comparison Summary

Feature	ClearVision	Cardius 1 and 2 XPO
Acquisition Types	SPECT and Gated SPECT	Same
Other Acquisition Types	None	Planar and Planar Gated
Number of Detectors	One or Two	One or Two
Detector Technology	Anger (33 photomultiplier tubes)	Solid-state
Crystal Material	NaI(Tl)	Csi(Tl)
Small Detector UFOV	Yes 8.5" x 8.5" UFOV	Yes 6.2" x 8.3" UFOV
Collimator	Inverse Fan-Beam	Parallel-Hole (LEHR)
NEMA Reconstructed Spatial Resolution with Scatter	9.8 mm (central) 7.6 mm (tangential) 8.4 mm (radial)	11.00 mm
NEMA System Sensitivity	147 cpm / uci	160 cpm / uci
NEMA Energy Resolution	≤ 9.0 %	< 10.5 %
Energy Range	90 – 160 keV	50 – 170 keV
Patient Position	Upright Chair	Upright Chair
Patient Weight Limit	≤ 500 lbs.	Same
Motor Driven Motions	1) Detector Tower Horizontal 2) SPECT Chair Rotation 3) SPECT Chair Vertical	1) SPECT Chair Vertical 2) SPECT Chair Rotation 3) SPECT Chair Horizontal
System Mount	Secured directly to floor.	N/A
Small Room Size	Yes 8' x 8'	Yes 7.5' x 8.0"
Processing Functions	SPECT and Gated SPECT processing and display, including SPECT reconstruction and cardiac reorientation.	SPECT, Gated SPECT, Planar, and Gated Planar processing and display, including SPECT reconstruction and cardiac reorientation.
SPECT Processing Software	Segami Mirage Release 5.6	Same

B.1.8 Conclusion

The ClearVision does not pose any new potential safety risks and performs as well as the predicate Digirad Cardius 1 and 2 XPO Systems. Therefore, it is the opinion of GVI Medical Devices that the ClearVision is substantially equivalent in terms of safety and effectiveness to the legally marketed Digirad Cardius 1 and 2 XPO Systems for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 25 2007

Mr. Kevin M. Murrock
Manager, Quality & Regulatory
GVI Medical Devices
1470 Enterprise Parkway
TWINSBURG OH 44087

Re: K072191
Trade/Device Name: ClearVision Nuclear Medicine Imaging System
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: August 3, 2007
Received: August 6, 2007

Dear Mr. Murrock:

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

B.2 Indication for Use

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510(k) Number (if known): K072191

Device Name: ClearVision Nuclear Medicine Imaging System

Indication for Use: The ClearVision nuclear medicine imaging system is intended for use as a diagnostic imaging device to acquire and process gated and non-gated Single Photon Emission Computed Tomography (SPECT) images.

Used with appropriate radiopharmaceuticals, the ClearVision system produces images that depict the anatomical distribution of radioisotopes within the myocardium.

Prescription Use ✓ (21 CFR Part 801 Subpart D) And/Or Over-The-Counter Use _____ (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072191