K080124

GE Medical System, F.I. , Haifa
4, Hayozma St. P.O. Box 170 Tirat HaCarmel 30200, ISRAEL

JAN 31 2008

10. 510(k) Summary of Safety and Effectiveness (in accordance to 21 CFR 807.87(h))

Summary date

December 27, 2007

Device Name

Proprietary Device Name: Ventri 1.1

FDA CDRH DMC

JAN 17 2008

Received

Establishment Name and Registration Number of Submitter

Name: GE Medical Systems F.I. Haifa
Registration Number: 9613299
Corresponding Official: Laurence Bigio; Site QA Manager
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Device Classification

Classification Name:	System Emission Computed Tomography (per 21CFR 892.1200)
Common Name:	Single Photon Emission Computed Tomography
Classification Code:	90 KPS
Panel Identification:	Radiology
Classification Class:	Class II Product

Type of Submission

Traditional

Reason for 510(k) Submission

Modification of legally marketed devices.

Identification of Legally Marketed Equivalent Devices

Ventri	K051855
D-SPECT™ Cardiac Scanner System	K062450
APEX Helix- A	K914807

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Device Description

The Ventri 1.1 is a high-performance Single Photon Emission Computed Tomography system, mainly for nuclear cardiology imaging.

Description of Change or Modification

The following modifications have been made to the Ventri 1.1 system relative mainly to the predicate device "Ventri" Nuclear Medicine System (K051855).

1. Gantry – the gantry structure is the same as Ventri (K051855). Relevant changes have been introduced in order to carry a new type of detection assembly.
2. Detection assembly – new type of detection assembly and electronic boards have been introduced. The special scanning geometry and detector technology, enable shorter scan times.
3. Table – the patient table is the same as Ventri (K051855).
4. Acquisition station – the acquisition station has been adapted from the Ventri system (K051855) with minimum configuration changes. Automatic gantry motion were reduced to minimum due to the fact that there are no moving parts during patient scanning. User interface (UI) is identical to that of the Ventri System (K051855).

Intended Use of Device

The intended use of the Ventri 1.1 system is to perform nuclear imaging procedures for detection and imaging of radioisotope tracer uptake in the patient body for clinical diagnostic purposes.
Ventri 1.1 is primarily intended for cardiac applications.

Summary of Studies

The system was tested to comply with safety industry standards (IEC60601 series) and its performance was tested according to industry performance standards (relevant parts in NEMA NU-1).
SW validation tests, Bench data and clinical images show that the Ventri 1.1 performance is substantially equivalent to the performance of the predicate devices.

Conclusion

In the opinion of GE Medical Systems F.I. Haifa, the Ventri 1.1 system is substantially equivalent in terms of safety and effectiveness to the legally marketed the Ventri Nuclear Medicine System (K051855).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 31 2008

GE Medical Systems F.I. Haifa
% Mr. Ned Devine
Senior Staff Engineer
Underwriters Laboratories, Inc.
333 Pfingsten Road
NORTHBROOK IL 60062

Re: K080124
Trade/Device Name: Ventri 1.1
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: January 11, 2008
Received: January 17, 2008

Dear Mr. Devine:

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

GE Medical System, F.I. , Haifa
4, Hayozma St. P.O. Box 170 Tirat HaCarmel 30200, ISRAEL

Indications for Use

510(k) Number (if known): K080124

Device Name: Ventri 1.1

Indications for Use:

The intended use of the Ventri 1.1 system is to perform nuclear imaging procedures for detection and imaging of radioisotope tracer uptake in the patient body for clinical diagnostic purposes.
Ventri 1.1 is primarily intended for cardiac applications

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)

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(Posted November 13, 2003)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K080124