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

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

Summary date

May- 16- 2005

Device Name

Proprietary Device Name: VENTRi

Establishment Name and Registration Number of Submitter

Name: GE Medical Systems F.I. Haifa
Registration Number: 9613299
Corresponding Official: Laurence Bigio; Quality, Safety and Regulatory Manager
GE Medical Systems F.I. Haifa
4 Hayozma St. P.O. Box 170
Tirat Hacarmel 30200, ISRAEL
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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

GE Quasar Nuclear Medicine System ("Infinia")	K022960
Optima Nuclear Medicine System	K915470
Millennium MT and Millennium MG Nuclear Medicine Systems	K962738

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Device Description

The VENTRi is a high-performance dual-head Single Photon Emission Computed Tomography system dedicated mainly for nuclear cardiology imaging.

Description of Change or Modification

The following modifications have been made to the VENTRi system relative to the predicate devices, Quasar ("Infinia") Nuclear Medicine System (K022960), Optima Nuclear Medicine System (K915470), and Millennium MT and Millennium MG Nuclear Medicine Systems (K962738).

1. **Gantry**: Gantry aperture has been expanded. A computer-controlled radial motion during the scan enables the detectors to perform non-circular SPECT orbiting for higher resolution scans. The new system utilizes lightweight construction relative to the predicate devices.

2. **Detectors**: The detectors contain PMT & electronics circuits that are similar to the Infinia (K022960) **Elite**™ Detector system, but with fewer PMTs. Twenty two 3" PM tubes and six 1.5" PM tubes are arranged above a NaI Crystal to create an acquisition F.O.V of 365x185mm. The front-end electronics of the Infinia (K022960) have been configured to adapt to the new number of PMT's with minor changes.

3. **Table**: Table designed to reduced size and includes telescopic mode motion in horizontal axis.

4. **Acquisition Station**: The Acquisition station has been adapted from the Infinia system (K022960), working in windows 2000 operating system and minor changes have been made to the SW.

Intended Use of Device

The intended use of the VENTRi system is to perform nuclear imaging procedures for detection and imaging of radioisotope tracer uptake in the patient body for clinical diagnostic purposes.
VENTRi is primarily intended for cardiac applications but also supports non-cardiac procedures of the patient's head, chest and body extremities.

Summary of Studies

Bench and images data show that the VENTRi images are similar to the images of The predicate devices.

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Conclusion

In the opinion of GE Medical Systems F.I. Haifa, the VENTRi system is substantially equivalent in terms of safety and effectiveness to the legally marketed the Quasar Nuclear Medicine System (K022960), Optima Nuclear Medicine System (K915470), and Millennium MT and Millennium MG Nuclear Medicine Systems (K962738).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 - 2005

GE Medical Systems F.I. HAIFA
% Mr. Alex Grob
Senior Project Engineer
Underwriters Laboratories, Inc.
Northbrook Division
333 Pfingsten Road
NORTHBROOK IL 60062-2096

Re: K051855
Trade/Device Name: Ventri
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: July 23, 2005
Received: July 25, 2005

Dear Mr. Grob:

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

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

STATEMENT OF INTENDED USE

510(k) Number (if known): K051855

Device Name: VENTRi

Indications for Use

The intended use of the VENTRi system is to perform nuclear imaging procedures for detection and imaging of radioisotope tracer uptake in the patient body for clinical diagnostic purposes. VENTRi is primarily intended for cardiac applications but also supports non-cardiac procedures of the patient's head, chest and body extremities.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use V
(Per 21 CFR 801-109)

OR Over-The-Counter Use_____

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051855