K033874

DEC 3 0 2003

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

Dec- 08- 2003

Device Name

Proprietary Device Name: MyoLIGHT

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 Code: 90 KPS
Panel Identification: Radiology
Classification Name: Emission computed tomography system (per 21CFR 892.1200)
Common Name: Nuclear Medicine Imaging system
Classification Class: Class II Product

Type of Submission

Traditional

Reason for 510(k) Submission

Modification of legally marketed device.

Identification of Legally Marketed Equivalent Devices

Nuclear Cardiology System: CARDIOSPECT D90 - K021823
(Manufactured by MEDISO Budapest)

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510(k) Summary of Safety and Effectiveness, MyoLIGHT, Page 2

Device Description
The MyoLIGHT system is a dedicated Gamma Camera for nuclear cardiology, high-performance dual-head nuclear medicine imaging system. It is based on the following legally marketed device: CARDIOSPECT D90 - K021823

Description of Change or Modification
The following modifications have been made to the MyoLIGHT system relative to the predicate device, CARDIOSPECT D90 (K021823):

1. Gantry: The gantry size has been reduced and adapted for the new patient table. The new system utilizes lightweight construction relative to the predicate device.
2. Detectors: The detectors move in an enclosed space on a fixed radius, and are set at 90 degrees to each other.
3. Table: The simplified patient table system is integrated to the gantry.
4. Acquisition station: The Acquisition station has been integrated into the gantry structure, including its operator console.
5. Built-in Gating Capability: The system includes built-in cardiac gating circuitry used for both gated planar and gated SPECT studies. This capability was provided externally in the predicate device. The two are functionally equivalent for nuclear medicine studies.

Intended Use of Device
The intended use of the MyoLIGHT system is to perform Nuclear imaging procedures for detection and imaging of radioisotope tracer uptake in the patient body for clinical diagnostic purposes.

Summary of Studies
Bench and images data show that the MyoLIGHT images are similar to the CARDIOSPECT D90 (K021823) images.

Conclusion
In the opinion of GE Medical Systems F.I. Haifa, the MyoLIGHT system is substantially equivalent in terms of safety and effectiveness to the legally marketed the CARDIOSPECT D90 (K021823) system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 3 0 2003

GE Medical Systems F.I. Haifa
% Ms. Chantel Carson
Engineering Group Leader
Underwriters Laboratories, Inc.
Northbrook Division
333 Pfingsten Road
NORTHBROOK IL 60062-2096

Re: K033874
Trade/Device Name: MyoLIGHT
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: 90 KPS
Dated: December 11, 2003
Received: December 15, 2003

Dear Ms. Carson:

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 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

510(k) Number (if known): K033874
Device Name: MyoLIGHT
Indications For Use:

The intended use of the MyoLIGHT system is to perform Nuclear imaging procedures for detection and imaging of single photon radioisotope tracer uptake in the patient body for clinical diagnostic purposes.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033874

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

(Optional Format 1-2-96)