D 510(k) Summary of Safety and Effectiveness

K023373

1470 Enterprise Parkway
Twinsburg, Ohio 44087
Phone: (330) 963-4083
Fax: (330) 963-4084

Date Prepared 1-October-2002

JAN 03 2003

Establishment Name and Registration Number

Manufacturer Name and Address:	GVI Medical Devices 1470 Enterprise Parkway Twinsburg, Ohio 44087
Contact:	Kevin Murrock
Telephone:	330-963-4083
Fax:	330-963-4084
E-mail:	mailto:kevin.murrock@gvitp.com
Registration Number:	None

Device Name and Classification

21 CFR Number:	892.1100
CDRH Product Code:	90 IYX
Regulatory Device Class:	I
Classification Panel:	Radiology
Proprietary Name:	OnePass Nuclear Imaging System
Common Name:	Gamma Camera System
Classification Name:	Camera, Scintillation (Gamma)

Reason for 510(k) Submission

New Device

Predicate Device

SIM-400 System, Scinticor, Inc.
510(k) Number: K931193

Device Description

The OnePass Nuclear Medicine Imaging Systems acquires and processes gated First Pass Radionuclide Angiography (FPRNA) images. After completion of acquisition, both qualitative and quantitative results are available to the physician for analysis.

The acquisition system consists of a single small field-of-view detector mounted on an articulating arm to allow precise positioning of the detector over the patient's heart. In addition, a vertical lift adjusts the detector height position to track changes in the incline of the treadmill to ensure camera remains positioned directly over the patient's heart during acquisition.

Intended Use

The OnePass nuclear medicine imaging system is intended for use as a diagnostic imaging device. Used with appropriate radiopharmaceuticals, it produces images that depict the anatomical distribution of radioisotopes within the human body. The OnePass 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.

The OnePass system's design is optimized for acquiring and processing cardiac first pass data. First-pass radionuclide angiography (FPRNA) is used to assess left and right ventricular function at rest or during stress.

Substantial Equivalence

The OnePass is of a comparable type and substantially equivalent to the Scinticor SIM-400 System (510(k) Number K931193). Both devices are used to perform First-Pass Radionuclide Angiography (FPRNA) studies and contain similar performance characteristics. The primary difference between the devices is that the OnePass is optimized for performing only FPRNA studies, while the SIM-400 is capable of performing additional study types such as cardiac SPECT.

Conclusion

The OnePass does not result in any new potential safety risks and performs as well as the SIM-400 for performing FPRNA studies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD. 20850

JAN 03 2003

Mr. Kevin M. Murrock
GVI Medical Devices
1470 Enterprise Parkway
TWINSBURG OH 44087

Re: K023373
Trade/Device Name: OnePass Nuclear Medicine Imaging System
Regulation Number: 21 CFR 892.1100
Regulation Name: Scintillation (gamma) camera
Regulatory Class: I
Product Code: 90 IYX
Dated: October 1, 2002
Received: October 8, 2002

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 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 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:

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" (21 CFR Part 807.97). 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

C Indications for Use Statement

510(k) Number (if known): K023373

Device Name: OnePass Nuclear Medicine Imaging System

Indications for Use: The OnePass nuclear medicine imaging system is intended for use as a diagnostic imaging device. Used with appropriate radiopharmaceuticals, it produces images that depict the anatomical distribution of radioisotopes within the human body. The OnePass 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801-109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023373