K972686

Appendix X

OCT 14 1997

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92 .

Prepared: August 20, 1996

Submitter: SMV America
8380 Darrow Rd.
Twinsburg, Ohio 44087
(800) 664-0844

Contact: W. Bishop
VP Business Development

Device:

Classification Name:	System, Emission Computed Tomography
Classification Number:	90 KPS
Common or Usual Name:	Coincidence Imaging Gamma Camera System
Trade/Proprietary Name:	VCAR option to DST Gamma Camera and VISION Powerstation VCAR option to DST-XL Gamma Camera and VISION Powerstation

Predicate Devices:

SPONSOR	**PRODUCT**	**Preamendment Status or 510(k) Number**
SMV America.	VCAR option to FX-80&PS	K963273
UGM Medical Systems, Inc.	Penn-PET (marketed as GE Quest 300)	K930428
ADAC Laboratories	MCD option to VERTEX Epic System	K952684

Device Description Summary:

The VCAR option to the DST Gamma Camera and VISION Powerstation (DST&PS/VCAR) and the VCAR option to the DST-XL Gamma Camera and VISION Powerstation are accessory upgrades to the previously cleared DST an DST-XL Gamma Cameras (K921008) and VISION Powerstation (K912753). This accessory enables the system to perform electronic collimation for positron emission tomography (PET) of radioisotopes within the human body. The DST&PS/VCAR and DST-XL&PS/VCAR utilize proprietary coincidence detection electronics and software to perform electronic collimation of gamma rays emitted from decay of radioisotopes in a patient. This process is called "Coincident Photon Emission Computed Tomography" (CPECT).

The DST&PS/VCAR and DST-XL&PS/VCAR allows the operator to acquire coincidence imaging data by controlling the detector electronics and processors in coincidence imaging mode. The DST&PS/VCAR and DST-XL&PS/VCAR also includes the control, processing, and display screens to perform reconstruction of 2-D and 3-D information from the acquired datasets.

Intended Use:

The VCAR option to the DST Gamma Camera and VISION Powerstation and the VCAR option to the DST-XL Gamma Camera and VISION Powerstation produce images which depict the anatomical distribution of radioisotopes within the human body, for interpretation by medical clinicians. The systems are intended for whole body nuclear imaging.

Technological Characteristics:

The DST&PS/VCAR and DST-XL&PS/VCAR have been designed to perform imaging of PET isotopes in a way which is very similar to traditional PET systems (e.g., the GE Quest 300) and gamma camera PET systems (e.g., SMV's VCAR option to the FX-80 Gamma Camera and Power Station, and ADAC's MCD option to the VERTEX Epic System). The DST&PS/VCAR and DST-XL&PS/VCAR is very similar to all three predicate devices.

Each system detects radioisotope emissions from the human body and integrates the acquired emission data over time to produce an image representing a quantification of emissions from the imaged region. All three units utilize the same theory of operation.

In all three systems, detection events from opposing detectors are compared, to determine if both detected an event almost simultaneously. Coincident events undergo additional processing to generate images which show the frequency of annihilation events due to radioisotopes in the area being imaged.

Each of the three systems have additional post-acquisition processing systems which further manipulate the image data to perform 2-dimensional and 3 dimensional reconstructions of the imaged area.

In addition, all three systems are able to utilize any FDA-approved positron-emitting radioisotope (e.g., Fluorodeoxyglucose [FDG]) to generate images.

Summary of Testing:

Major performance parameters have been measured using industry-standard test methods to determine that the device meets its system performance specifications and performs in a fashion similar to predicate devices.

Conclusion:

The VCAR option for the DST and DST-XL Gamma Cameras and VISION Powerstation was developed and validated in accordance with the Company's product and software development procedures. System testing and validation demonstrates that the system meets its published specifications, performs as well as or better than the currently marketed product, and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 14 1997

William Bishop
Vice President of Business Development
SMV America
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Twinsburg, OH 44087

Re: K972686
VCAR option to the DST and DST-XL
Gamma Cameras and VISION
Powerstation Computer
Dated: July 16, 1997
Received: July 17, 1997
Regulatory Class: II
21 CFR 892.1200/Procode: 90 KPS

Dear Mr. Bishop:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

William Yin

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K-972686

Device Name: VCAR option to DST & DST-XL Gamma Cameras and Visual Powerstation computer.

Nuclear Medicine Device

Indication For Use: To detect or image the distribution of radionuclides in the body or organ, using the following technique(s).

	YES	NO	Energy Range (keV)
A. Planar imaging	—	—	—
B. Whole body imaging	X	—	60 - 560 KeV
C. Tomographic imaging (SPECT) for non Positron emitter	—	—	—
D. Positron imaging by coincidence	X	—	60 - 560 KeV
E. Positron imaging without coincidence	—	—	—
F. Other indication(s) in the device label, but not included in above list	Indication for use of the VCR option to the DST and DST-XL cameras and Powerstation computer is as an accessory upgrade intended to perform electronic collimation for coincidence imaging of positron-emitting radioisotopes in the human body.		

(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)

(Optional Format 1-2-96)

David A. Seguson
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K972686