Section D. 510 (k) Summary of Safety and Effectiveness

The following information is in conformance with 21 CFR 807.92. K991565

Date Prepared:	March 11, 1999
Manufacturer:	SMV America 8380 Darrow Road Twinsburg, Ohio 44087 (330) 425-1340 (330) 405-7682
Contact:	Philip Vernon (extension 6018)
Proprietary name:	TAC-2, Transmission Attenuation Correction and DST, DST-XL Gamma Cameras and VISION Power Station computer (K921008, K942837, K912573), for use in single photon mode and in conjunction with VCAR (Coincidence) option (K972686).
Common names:	Attenuation correction
Classification name:	System, Emission Computed Tomography
Predicate device:	(K952190) 90KPS TAC SMV (K971980) 90 KPS MCD-AC ADAC Laboratories
Device Description:	The TAC-2 hardware consists of two sliding line source emitter block/collimator assemblies. Each assembly extends transaxially across the face of each detector of a DST series gamma camera oriented 180°. When in use each emitter block exposes the collimator in the opposing assembly. The assemblies travel in synchrony along the axial direction.
Intended Use:	The TAC-2 accessory to the DST and DST-XL Gamma Cameras and VISION Power Station produces images that depict the anatomy of a patient. The accessory is intended to provide an enhancement to emission images acquired using the in SPECT mode or using the VCAR option to the DST and DST-XL Gamma Cameras by correcting for photon attenuation effects of the patient's anatomy.

Technological Comparison:	TAC-2 is similar to the TAC and MCD-AC in that all devices measure attenuation using external transmission radionuclide sources. In each device, the transmission data acquired is used to form attenuation maps to correct emission data for attenuation. The transmission radionuclide of TAC-2 (^{153}Gd) is the same as in TAC, but is different from MCD/AC (^{137}Cs). The lower energy emissions from ^{153}Gd) provide transmission images with increased contrast of bone, soft tissue and lung. The source geometry is also different in that MCD-AC uses point sources while TAC and TAC-2 use line sources
Testing:	Clinical and non-clinical studies were conducted using the TAC-2 attenuation correction device with a DST-XL with the VCAR option. Images produced were of the same quality as those provided by the manufacturers of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 2 1999

Philip Vernon
SMV America
A Nuclear Medicine Company
8380 Darrow Road
Twinsburg, Ohio 44087

Re: K991565
TAC-2 option for use with DST,
DST-XL Gamma Cameras
Dated: April 21, 1999
Received: May 5, 1999
Regulatory Class: II
21 CFR 892.1200/Procode: 90 KPS

Dear Mr. Vernon:

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 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). 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 requirements, 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/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section E. Indications for Use Form

510(k) Number (if known): K991565

Device Name: TAC-2

Indications For Use:

The SMV TAC-2 accessory to the SMV dual head emission tomographic systems produces images of a patient's anatomy when performing cardiac or wholebody imaging in single photon mode, or in coincidence mode (using the VCR option) . The system is intended to provide an enhancement to the emission images by compensating for the attenuation effects of the human body.

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

Concurrence of CDRH, Office of Device (ODE)

David A. Clayman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991565

Prescription Use ✓
(Per 21 CFR 09)

(Optional Format 3-10-98)