JUN 18 1999

K991318

Attachment 1
Summary of Safety and Effectiveness

*Attachments labeled "CONFIDENTIAL" as follows: Hitachi Medical Corporation regards the information defined as part of this Attachment to be a trade secret and confidential in nature.

K991318

1.0 Submitter Information

Hitachi Medical Corporation of America
Nuclear Medicine Product Division
9177 Dutton Drive, Twinsburg, Ohio
ESTABLISHMENT REGISTRATION NUMBER: 1530450
PH: 330-405-3330
FX: 330-405-3222

Contact
Gary W. Enos

Date
April 16, 1999

2.0 DEVICE NAME: *Convergence*℠ *NUA*℠

Classification Panel: Radiology
Classification Name: System, Tomographic, Nuclear
Classification Number: 892.1200 **90KPS**
Trade/Proprietary Name: ***Convergence***℠ ***NUA***℠ for Hitachi *SPECTRA*Digital™ *V*250DSP Gamma Cameras

Predicate Device: ADAC Vantage ExSpect 2.1 system cleared under **K971878**

3.0 Device Description

Function

Convergence℠ ***NUA***℠ for Hitachi *SPECTRA*Digital™ *V*250DSP Gamma Cameras is an optional Attenuation Correction Device (ACD) that provides capability to map anatomical information using external radioactive line source transmission, analyze densities and assign patient specific attenuation coefficients to minimize distortion caused by false information in the emission computer tomographic images due to overlying tissue and undesired scattered photons. The device is a combination of hardware and software to provide transmission, collimation, acquisition and analysis/correction of ECT data.

The Hardware which consists of a single, non-moving line source holder equipped with shutter, special line source slat collimation to minimize patient exposure and axial scatter and fan beam collimation. The standard source is Gadolinium 153 (240.4d T1/2, 97.4~103.2 keV, while the system has been confirmed with Technetium 99m (6hr T1/2, 140.5 keV) and Cerium-139 (137.6d T1/2, 165.8 keV).

The software consists of camera based transmission acquisition control and workstation based OSEM iterative and/or FBP (Filtered Back-Projection) reconstruction, coefficient determination and correction to ECT slice data. The system uses the same camera mechanical platform, table, collimators, electrical system and acquisition/system operating software cleared under **K954129**, with the addition of acquisition/processing sequences to correct for scatter and effects of

attenuation. The acquisition of transmission and emission data is performed via fast sequential orbit acquisition to minimize effects of cross-spill and cross talk. A detailed description can be found in Attachment 1. Detailed device specifications can be found in Attachment 4.

Scientific Concepts:

Over lying anatomical structures of varied densities and in-patient scatter are known to cause distortion to the determination of radionuclide distribution(s) in-vivo. Spatial and contrast representation of radionuclide distribution is degraded by photon attenuation and scatter. Fixed geometrical and linear attenuation corrections (ie. Chang and Sorenson methods) are simple estimations. In addition, attempts to manage the effects of scatter via pre and/or post **scatter sampled window** subtraction techniques serve to perturb Poisson noise statistics and reconstruction weighting values contributive to tomographic results.

A more accurate method of attenuation and scatter correction has been the basis for patient specific transmission imaging and spectral scatter window sampling techniques. Fan beam acquisition and reconstruction is documented to improve geometrical sensitivity and resolution limited only by the intrinsic resolution of the camera system and the solid angle of the focal distance of the collimator. For transmission imaging, the diameter of the line source is an additional consideration to the resolution achievement potential. Utility of longer focal length symmetric fan beam collimation (77cm) positioned offset to the axis of rotation mimics asymmetric fan beam geometry, thereby markedly increasing the viewing volume to reduce potential for truncation.

In combination with Iterative ML-EM and OSEM reconstruction methods (known to accurately incorporate the Poisson nature of photon noise and a number of other relevant physical factors), improved tomographic results in terms of image contrast and quantitative accuracy are well documented via Monte-Carlo, phantom and real patient conditions. The combination of documented and proven Fan Beam acquisition and reconstruction and well collimated line source geometry, improvements in data acquisition density (Signal-to-Noise) and resolution input function provide an accurate basis for transmission and emission volume correlation.

The ***Convergence℠ NUA℠*** for Hitachi *SPECTRA*Digital™ *V*250DSP Gamma Cameras is an Attenuation Correction Device (ACD) incorporates the applied improvements of offset fan beam (1/2 fan) acquisition/reconstruction, single line non-moving source, axial collimation, OSEM iterative reconstruction, scatter window sampled correction and density specific attenuation correction to emission ECT tomographic distributions.

5.0 Device Technological Characteristics:

Technologies associated with ***Convergence℠ NUA℠*** for Hitachi *SPECTRA*Digital™ *V*250DSP Gamma Cameras are defined in Attachment 4. Key elements include:

- Symmetric Fan Beam Collimation with a 77cm, focal length
- Utilization of offset fan beam parameters and detector/collimator orientation to minimize truncation and increase viewing volume (increase the TCT FOV)
- Axial collimated line source of NRC registered and approved sources in the 1.5~3mm diameter range
- Shutter controlled transmission with absorber plates to manage source strength, transmission beam characteristics (area and profile)
- Sequentially acquired Transmission and Emission data to minimize cross contamination
- Scatter window sampling to modulate transmission and emission data as part of the reconstruction domain.
- OSEM iterative reconstruction of transmission and emission data to maximize resolution and quantification accuracy.
- Segmentation of anatomical regions and anatomical densities to correct attenuation effects in emission SPECT.

6.0 Testing and Equivalence

In the code implementation, simulation and phantom processed studies, acquisition, analysis and correction results have been thoroughly tested and verified to operate properly and as intended. The results of transmission reconstruction and attenuation coefficient determination has proven effective. Clinical tests have documented effective application and expected results consistent with predicate devices currently in commercial distribution.

Hitachi Medical believes the ***Convergence***℠ ***NUA***℠ for Hitachi *SPECTRA*Digital™ *V*250DSP Gamma Cameras, an Attenuation Correction Device (ACD), to be substantially equivalent to Gamma Camera Systems currently in commercial distribution in the U.S. We have tested the ***Convergence***℠ ***NUA***℠ for Hitachi *SPECTRA*Digital™ *V*250DSP Gamma Cameras with the Data Spectrum Anthromophic Phantom, Data Spectrum Delux 5000 SPECT Phantom, Data Spectrum Cardiac Phantom and NEMA Scatter Phantom to establish the basis for proper operation.

In accordance with NUREG-1556 of the Nuclear Regulatory Commission for emitter source devices, the devices emissions, leakage, patient dose and safe controls are consistent with requirement and those of commercially approved devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 18 1999

Gary W. Enos
Hitachi Medical Corporation
9177 Dutton Drive
Twinsburg, Ohio 44056

Re: K991318
Convergence NUA for SpectraDigital
V250DSP System
Dated: April 16, 1999
Received: April 19, 1999
Regulatory class: II
21 CFR 892.1200/Procode: 90 KPS

Dear Mr. Enos:

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

510(k) Number (if known): K991318

Device Name: ***Convergence*℠ *NUA*℠** for Hitachi *SPECTRA*Digital™ *V*250DSP Gamma Cameras

Indications For Use:

Intended uses of ***Convergence*℠ *NUA*℠** for Hitachi *SPECTRA*Digital™ *V*250DSP Gamma Cameras is identical to the ADAC Vantage ExSPECT 2.1 cleared under **K971878** in system function and operational software. These include:

- Acquisition of patient specific anatomic density via transmission imaging to determine attenuation coefficients applicable to emission slice data.
- Reconstruction of transmission and emission SPECT data via FBP and/or ML-EM/OSEM reconstruction methods
- Analysis and generation of attenuation maps and coefficients to apply to emission SPECT slice/volume sets.

The acquisition of SPECT is as cleared under *SPECTRA*Digital™ Series *V*250DSP system **K954129**, with addition of transmission acquisition protocols to produce images which depict anatomical density of a patient. The device is intended to provide an enhancement to the emission images acquired *SPECTRA*Digital™ Series *V*250DSP by correcting for attenuation and scatter effects in the patient. When resulting images are interpreted by a trained physician, the information provided can be useful in the diagnosis determination.

Imaging capabilities with ***Convergence*℠ *NUA*℠** for Hitachi *SPECTRA*Digital™ *V*250DSP Gamma Cameras option include:

- All SPECT procedures in common practice including matrix based spatial framed, temporal/spatial list mode and angular projection mode static, gated and multi-orbit sampling
- High and normal count-rate dynamic and non-temporal SPECT
- In conjunction with additional options for Coincidence based imaging, the detector performance and NUA℠ acquisition and processing characteristics are available for non-uniform attenuation SPECT, attenuation correction in CID and CID based ECT imaging (these options are covered under separate and exclusive PMAs)
- Multiple window sampled imaging, including scatter correction via single, dual or plural window processing.

(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)

David A. Legorm

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K991318

(Optional Format 1-2-96)