

JUL 30 1999

K991535

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.

1.0 Submitter Information

Hitachi Medical Corporation of America
Nuclear Medicine Product Division
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ESTABLISHMENT REGISTRATION NUMBER: 1530450
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Contact

Gary W. Enos

Date

April 30, 1999

2.0 DEVICE NAME: **ConvergenceSM CDRSM**

Classification Panel: Radiology

Classification Name: System, Tomographic, Nuclear

Classification Number: 892.1200 **90KPS**

Trade/Proprietary Name: **ConvergenceSMCDRSM** for Hitachi
SPECTRADigital™ V250DSP Gamma Cameras

Predicate Device: ADAC EPIC-MCD cleared under K952684, ADAC MCD-AC cleared under K971980 and ADAC VERTEX Ultra cleared under K982911.

3.0 Device Description

Function

CONVERGENCESM CDRSM for Hitachi **SPECTRADigital™ V250DSP Gamma Cameras, cleared under K954129** is an Coincidence Imaging Device (CID) option that provides capability to acquire 511 keV coincidence events and form images in 1D, 2D and 3D modes of operation. With the addition of ATTCOR, non-linear scaled low energy transmission correction utilizing NUASM (**NUASM submitted under K991318**) mapping of anatomical information using external radioactive line source transmission with analysis of densities and assignment of patient specific attenuation coefficients to minimize distortion due to overlying tissue and undesired scattered photons. The device is a combination of hardware and software to provide detection, decoding, image formation with corrections, and Whole body and tomographic reconstruction. When the system is equipped with thicker 5/8" crystals submitted under **K991129**, the V250DSP efficiency for 511 keV events is improved.

The additional Hardware which consists of Aperture Grids with graded absorbers, high speed pre-amps with coincident signal timing, high speed decoding and correction circuitry and acquisition control software. 1-D framing at the camera system is provided and 2-D, 3-D frame formation via workstation based FORE (Fourier Rebinning) and OS-EM processes. When equipped with ATTCORSM, a single, non-moving line source holder equipped with shutter, special line source slat

collimation to minimize patient exposure and axial scatter and non-linear scaling processing is provided. The software consists of FORE rebinning, OSEM iterative and/or FBP (Filtered Back-Projection) reconstruction, transmission acquisition control and coefficient determination in the correction to ECT slice data per **NUASM submitted under K991318**. A detailed description can be found in Attachment 1. Detailed device specifications can be found in Attachment 4.

Scientific Concepts:

Coincidence detection with large field of view crystal devices is not new, dating to the late 1960's. Publications by Muehllehner and Jaszczak in the early 1970's cited Positron Imaging utilizing plural coincidence detector channels and graded radiation absorbers. Recent development of higher performance "multi-range" pre-amplification and digital decoding has combined with new rebinning algorithms to provide reasonable 511 keV image reformation efficiency.

Improved baseline restoration and pile-up rejection circuits have become part of the pre-digitization of PMT signals, permitting digitizers and DSP (digital signal processor) based decoding to operate on higher quality and data rate signals rising from 511 keV events. With the addition of pre-digitization coincidence determination (30~50 nS timing), signal integration and decoding is limited to qualified events to maximize efficiency. The use of DSP based corrections (linearity, uniformity, energy) maximizes signal processing at higher singles and coincident count rate performance.

To maximize countrate and minimize randoms/scatter, the use of graded absorber plates (Lead-1.0mm, Copper-0.5mm, Steel-1.0mm layers) prior to crystal entrance, ensures count processing to energies above 300keV and reduces associated off axis oblique and randoms scatter. Further, to reduce axial emissions and reduce random events, Aperture Grids (isotropic solid angle restrictors) fixed to the detectors act in a similar manner to extended septa in dedicated PET devices. The utility of CFD (delay timing windows @ 200nS-300nS) are used to differentiate TRUE coincidence from Randoms.

511 keV event detection is more efficient in thicker NaI(Tl), which has established growing interest in the option of 5/8" scintillators (optional to 3/8" which are standard in most systems and submitted for SPECTRADigital V250DSP under **K991129**).

Coincidence events in 1D (perpendicular to both detectors) are framed by the camera system without need for external rebinning. In 2D and 3D modes, the camera event processes are list mode streamed and subjected to FORE (First Order Fourier Rebinning Approximation) for framing. Subsequent processing for tomographic, WholeBody and correction of attenuation effects are managed with well documented OS-EM and attenuation mapping routines (submitted for SPECTRADigital V250DSP under **K991318**). The non-linear scaled low energy transmission maps to 511 keV application, however the effect and basis is similar to **NUASM submitted under K991318**.

The **ConvergenceSM CDRSM** for Hitachi **SPECTRADigital™ V250DSP** Gamma Cameras is a Coincidence Imaging Device (CID) option that provides capability to acquire 511 keV coincidence events and form images in 1D, 2D and 3D modes of operation.

5.0 Device Technological Characteristics:

Technologies associated with **ConvergenceSM CDRSM** for Hitachi **SPECTRADigital™ V250DSP** Gamma Cameras are defined in Attachment 4. Key elements include:

- ◆ Aperture Grids to restrict incident angle of coincidence, scatter and randoms in 1D, 2D and 3D operation.
- ◆ Graded Absorber Plates for removal of oblique and scattered photons.
- ◆ New designed pre-amps, decoder and correction circuits to provide coincidence/random timing and discriminated signals for integration. Camera system framing in 1D and List mode event description in 2D and 3D are transformed via FORE rebinning for additional processing.
- ◆ Axial collimated low energy line source of NRC registered and approved sources in the 1.5~3mm diameter range
- ◆ Utilization of offset fan beam parameters and detector/collimator orientation to minimize truncation and increase viewing volume utilizing the Aperture Grids (increase the TCT FOV).
- ◆ 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 **ConvergenceSM CDRSM** for Hitachi **SPECTRADigital™ V250DSP** Gamma Cameras, a Coincidence Imaging Device (CID) option, to be substantially equivalent to Gamma Camera Systems currently in commercial distribution in the U.S. We have tested the **ConvergenceSM CDRSM** for Hitachi **SPECTRADigital™ V250DSP** Gamma Cameras with the Data Spectrum Delum 5000 Phantom, Data Spectrum PET 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.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Gary W. Enos
Hitachi Medical Corporation of America
Nuclear Medicine Products Division
9177 Dutton Drive
Twinsburg, Ohio 44087Re: K991535
CONVERGENCE CDR Coincidence
Detection Reconstruction for Hitachi
SPECTRA Digital™ V250DSP Digital
Dual Detector Gamma Camera System
Dated: April 30, 1999
Received: May 4, 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): K991535

Device Name: **ConvergenceSM CDRSM** for Hitachi **SPECTRADigitalTM V250DSP**
Gamma Cameras

Indications For Use:

Intended uses of **ConvergenceSM CDRSM** for Hitachi **SPECTRADigitalTM V250DSP** Gamma Cameras is identical to the principle of coincidence imaging used by EPIC-MCD cleared under K952684, ADAC MCD-AC cleared under K971980 in intended use, methods, reconstruction algorithms, transmission source type, and effectiveness of application. These include:

- ◆ Acquisition of patient specific biodistribution of positron-emitting radioisotopes in-vivo.
- ◆ Acquisition of patient specific anatomic density via transmission imaging to determine attenuation coefficients applicable to emission slice data.
- ◆ Reformation of coincidence data to images frames with subsequent reconstruction of transmission and Wholebody ECT data via FBP and/or ML-EM/OSEM reconstruction methods.
- ◆ Analysis and generation of attenuation maps and coefficients to apply to emission ECT slice/volume sets.

Imaging capabilities with **ConvergenceSM CDRSM** for Hitachi **SPECTRADigitalTM V250DSP** 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
- Use in conjunction with FDA approved 511 keV emitting radiopharmaceuticals
- High and normal count-rate dynamic and non-temporal ECT
- In conjunction with Coincidence based imaging, the detector performance and NUASM acquisition and processing characteristics are available for non-uniform attenuation ECT, attenuation correction in CID and CID based ECT imaging.
- 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 CDHR, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

Dina M. Flynn
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K991535

(Optional Format 1-2-96)