

MAY 13 1999

K991129

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.

00004

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

March 29, 1999

2.0 DEVICE NAME: *SPECTRADigital™* Series V250DSP Gamma Camera System

Classification Panel: Radiology

Classification Name: System, Tomographic, Nuclear

Classification Number: 892.1310 **90JWM**

Trade/Proprietary Name: Hitachi *SPECTRADigital™* V250DSP Gamma
Camera System with thick NaI(Tl) crystal

Predicate Device: *SPECTRADigital™* Series V250DSP cleared under **K954129**
and other gamma camera systems cleared with 5/8" crystals

3.0 Device Description

Function

The *SPECTRADigital™* series gamma camera systems are area detectors designed to detect gamma rays emitted from the decay of radioisotopes injected into a patient. The position of the decay is calculated (a ray from the event to the detector) by the system, and stored. The positions of a large number of decay events forms an electronic image of the location of the radioactive material. This image can be displayed on a CRT or transferred to photographic film for review. The collection of data at multiple detector positions allows three dimensional information to be obtained by tomographic means. The addition of thicker NaI(Tl) crystals enhance efficiency of detection at higher energies with minimal loss of imaging performance over energy ranges used routinely.

The software did not need to be modified or revised to support this option.

Scientific Concepts:

Diagnostic Nuclear Medicine began in the early 1950's with the availability of short half-life radioisotopes. Isotopes such as I^{131} were injected into the patient and were selectively taken up by organ systems such as the thyroid.

Measurement of the resulting radioactivity in the organ provided information on both the size of the organ and the relative amount of the isotope taken up.

Nuclear Medicine cameras work on a principle similar to television cameras. A collimator (lens) "focuses" gamma rays on a scintillation crystal. The scintillation crystal converts the gamma rays into light. Photomultiplier tubes are then used to convert the light into an electrical signal proportional to the energy of the detected gamma ray. Early instruments used a single hole lead collimator and detector that was moved in a raster pattern forming a 2-D image of the organ of interest. In the late 1950's methods were developed for directly obtaining a 2-D image by using a large crystal with multiple photomultiplier tubes and electronically calculating the position and energy of the gamma event.

Two dimensional projections collected at many positions can be mathematically combined to yield a three dimensional representation of the data. This principle of tomographic reconstruction was discovered early in this century, but it was not until the advent of high speed digital computer that the technique could be successfully applied in diagnostic imaging first to CT then to Nuclear Medicine and MRI.

Physical And Performance Characteristics:

Nuclear Medicine is currently of great interest because of its high contrast, and relatively low cost per study. The ability to attach radioisotopes to substances that are selectively taken up by specific tissue types can provide very high contrast between the tissue or organ of interest and surrounding tissue. This has tended to compensate for the relatively poor spatial resolution of Nuclear Medicine compared to other modalities such as MRI.

In addition the uptake and clearing of the radioisotopes can be observed temporally, providing an indication of the biological activity of the tissue. This is important when attempting to determine tissue viability, or finding areas of abnormal activity such as cancerous tissue.

4.0 Device Intended Use:

The intended uses of the *SPECTRADigital™ V250DSP* with 5/8" crystal option is identical to the *SPECTRADigital™ Series V250DSP* cleared under **K954129**.. SPECT images are acquired over 360 degrees of orbit and transferred to a computer for processing. With 90° detector mechanical positioning in addition to standard 180° opposed positioning, cardiac SPECT imaging can be acquired with added efficiency during 180° orbit acquisition. Wholebody (head to foot) images are key applications of the SpectraDigital™ systems due to their large rectangular fields of view. Organ systems are imaged to assist in the determination of functional or pathological disorders including those affecting: Brain, Bone, Heart, Liver, Renal, Lung, Thyroid, Gallbladder, Pancreas, Testicular, and circulatory systems. Some diseases or pathology defined using customary techniques and industry approved radiopharmaceuticals include oncologic (cancer), bloodflow, tissue viability, TIA, infarction, embolism,

thyroiditis, cirrhosis. The addition of thicker NaI(Tl) crystal increases the detection efficiency for higher energy applications.

5.0 Device Technological Characteristics:

Identical to the predicate device

6.0 Testing and Equivalence

Hitachi Medical believes the *SPECTRADigital™* Series V250DSP to be substantially equivalent to Gamma Camera Systems currently in commercial distribution in the U.S. We have compared the Hitachi *SPECTRADigital™* V250DSP Gamma Camera System with thick NaI(Tl) crystal to the standard *SPECTRADigital™* V250DSP system with 3/8" crystal system cleared under **K954129** utilizing NEMA NU1-1994 standards



MAY 13 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Gary W. Enos
General Manager
Hitachi Medical Corporation of America
Nuclear medicine Products Division
9177 Dutton Drive
Twinsburg, Ohio 44087

Re: K991129
SPECTRADigital Series V250DSP
Gamma Camera System Thick Crystal Option
Dated: March 29, 1999
Received: April 2, 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): K 991129

Device Name: **Hitachi SPECTRADigital™ V250DSP Gamma Camera System**
with thick (5/8") NaI(Tl) crystal

Indications For Use:

The SPECTRADigital™ Series V250DSP system with 5/8" crystal option are identical to the intended uses of the SPECTRADigital™ Series V250DSP camera cleared under **K954129** including acquisition of SPECT, planar, and wholebody imaging of all organ systems utilizing FDA approved radiopharmaceuticals in the energy range from 50 to 511 keV. When resulting images are interpreted by a trained physician, the information provided can be useful in the diagnosis determination.

Imaging capabilities with the Thick Crystal (5/8") NaI(Tl) option include:

- All SPECT and Planar 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 planar and SPECT
- In conjunction with additional options for Coincidence and transmission based imaging, the detector performance and 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)

David A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991129

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

00009