K971186

AUG - 8 1997

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. General Information

A. Submitted By:

ADAC Laboratories
540 Alder Drive
Milpitas, CA 95035
Tel: (408) 321-9100
Fax: (408) 321-9686

Contact Person: Dennis Henkelman at address above

B. Device Trade Name: Vantage 2.0 ExSPECT
Common Name: Gamma Camera Systems
Classification Name: System, Emission Computed Tomography

C. Predicate Device: Vantage 1.0

D. Device Description:

Vantage 2.0 ExSPECT is a software program which will be marketed as an optional addition to ADAC Laboratories Gamma Camera products. This is a modification of the Vantage 1.0 software package, cleared in 510k K943596.

Vantage 2.0 ExSPECT is a computer program that provides a patient's anatomical information using the external radioactive scanning line sources with special collimation to minimize patient exposure, and the acquisition electronics and software, cleared in 510k K943596 for Vantage 1.0.

The system uses the same imaging technique of Single Photon Emission Computed Tomography (SPECT) with attenuation correction, as in Vantage 1.0, but adds image quality enhancements by correcting for the Photopeak scatter, Downscatter, and Resolution Recovery (RR).

E. Indications for Use:

The Vantage 2.0 ExSPECT option to the ADAC Gamma Camera Systems produces images which depict the anatomical density of a patient. The system is intended to provide an enhancement to the emission images acquired using the ADAC Gamma Camera Systems by correcting for attenuation effects in the patient.

F. Technological Comparison:

The Vantage 1.0 and Vantage 2.0 ExSPECT devices have the same indications for use, source type and geometry, system hardware, operating principles, and reconstruction algorithms, with the exception of minor modifications to the reconstruction algorithm to better account for resolution recovery and Photopeak and down scatter.

II. Testing

Images were acquired using the protocol outlined in the Vantage user manual.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 8 1997

Dennis W. Henkelman
Director, Regulatory Affairs
and Quality Assurance
ADAC Laboratories
540 Alder Drive
Milpitas, California 95035

Re: K971878
Vantage 2.0 ExSPECT Gamma Camera
Dated: May 19, 1997
Received: May 21, 1997
Regulatory Class: II
21 CFR 892.1200/Procode: 90 KPS

Dear Mr. Henkelman:

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,

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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: Vantage 2.0 ExSPECT

Sponsor Name: ADAC Laboratories

Indications For Use:

The Vantage 2.0 ExSPECT option to the ADAC Gamma Camera Systems produces images which depict the anatomical density of a patient. The system is intended to provide an enhancement to the emission images acquired using the ADAC Gamma Camera Systems by correcting for attenuation effects in the patient.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) ()
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K971878

Prescription Use ☑
Over-The-Counter Use ☐