K991607

JUL 26 1999

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. General Information

A. Submitted by:

ADAC Laboratories
540 Alder Drive
Milpitas, California 95035
Tel: (408) 468-3989
Fax: (408) 435-7427

Contact Person: Dennis W. Henkelman at address above

B. Device Trade Name: Vantage 2.5
Common Name: Gamma Camera Systems
Classification Name: System, Emission Computed Tomography

C. Predicate Device: Vantage 2.0

D. Device Description:

Vantage 2.5 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 2.0 ExSPECT software package, cleared in 510(k) K971878.

Vantage 2.5 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 510(k) K943596 for Vantage 1.0 and in 510(k) K971878 for Vantage 2.0 ExSPECT.

The system uses the same imaging technique of Single Photon Emission Computed Tomography (SPECT) with attenuation correction, as in Vantage 2.0 ExSPECT, but adds Quality Assurance (QA) Tools by using Pre-Scan, Automatic Energy Window Checking and Transmission QA Reference.

E. Indications for Use:

Vantage 2.5 is a software program, which will be marketed as an addition to ADAC Laboratories Gamma Camera products. This is a modification of the Vantage 2.0 ExSPECT software package, cleared in 510k K971878.

F. Technological Comparison:

The Vantage 2.0 ExSPECT and Vantage 2.5 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 acquisition software.

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

JUL 26 1999

Dennis W. Henkelman, R.A.C.
Director, Regulatory Affairs & Quality Assurance
ADAC Laboratories
540 Alder Drive
Milipitas, California 95035

Re: K991607
Vantage 2.5 Gamma Camera System
Dated: May 7, 1999
Received; May 10, 1999
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 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): K991607

DEVICE NAME: Vantage 2.5

INDICATIONS FOR USE:

Vantage 2.5 is intended to provide quality assurance enhancements to nuclear medicine images acquired using the ADAC Gamma Camera Systems. It includes scatter correction capability for ^{99m}Tc.

(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) (Optional Format 1-2-96)

David G. Seyer

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991607