

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) 321-9629
- Contact Person: Dennis Henkelman at address above
- B. Device Trade Name: Vertex Ultra
Common Name: Gamma Camera System
Classification Name: System, Emission Computed Tomography
- C. Predicate Device: Siemens E.CAM Profile AC
Millennium MT & MG

D. Device Description:

Vertex Ultra is a gantry (ring type) device designed for single- or dual-detector nuclear imaging accommodating a broad range of emission computed tomography (ECT) studies. The device includes the gantry frame, two detectors, a collimator storage cabinet with acquisition computer unit, a patient imaging table, and a remote hand controller. The Vertex Ultra gantry is an "open" frame permitting easier access for imaging of standing, seated, and supine patients. The patient imaging table (pallet) is mechanized for patient loading access and for movement during imaging studies; or the pallet may be removed by the operator for imaging of patients in wheelchairs, beds, or gurneys.

Vertex Ultra is designed to allow acquisition of a broad range of imaging studies using single or dual detectors. When using either a single detector or dual detectors placed in relative 90° or relative 180° positions (as study appropriate),

static, dynamic, gated, total body and ECT studies (circular orbit), non-circular orbital ECT, coincidence imaging, and gated SPECT (circular and non-circular orbit) imaging studies can be performed with or without a previously cleared ADAC attenuation correction option. In addition, Vertex Ultra acquisition software can be programmed to complete multiple imaging studies called protocol strings, which involve a combination of several imaging studies collected for use in customized clinical procedures.

E. Indications for Use:

Vertex Ultra is intended to produce images depicting the anatomical distribution of single photon and positron emitting radioisotopes within the human body for interpretation by medical personnel.

F. Technological Comparison:

Vertex Ultra, Siemens E. CAM, and GE Millennium have similar indications for use as well as open and/or ring type gantries and pre-programmed detector motions, and perform the same type of study acquisitions.

II. Testing

Flood phantom images were produced to demonstrate acceptable field uniformity. In addition, center of rotation (COR) testing was performed to verify proper alignment.



NOV 16 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Dennis W. Henkelman
Director, Regulatory Affairs and Quality Assurance
ADAC Laboratories
540 Alder Drive
Milpitas, CA 95035Re: K982911
Gamma Camera System
Dated: August 17, 1998
Received: August 18, 1998
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 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,

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): K982911

Device Name: Vertex Ultra

Sponsor Name: ADAC Laboratories

Indications for Use

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
Over-The-Counter Use

David H. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K982911