K971980

OCT 23 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: MCD-AC
Common Name: Gamma Camera Systems
Classification Name: System, Emission Computed Tomography

C. Predicate Device:

Vantage 1.0
EPIC-MCD
UGM 240H
GE ADVANCE

D. Device Description:

MCD-AC is a system that will be marketed as an optional addition to the ADAC EPIC-MCD Gamma Camera System (e.g., Vertex, Vertex+, any other ADAC camera in a dual-head configuration which can take 180° images). MCD-AC is short for Molecular Coincidence Defection Attenuation Correction, and is a modification to the EPIC-MCD system, cleared in 510k K952684.

The MCD-AC uses the same principle of coincidence imaging used by the EPIC-MCD, but adds the image quality enhancing feature of attenuation correction. When a radioactive material is administered to a patient and the resulting gamma ray emission detected, attenuation is observed due to the internal parts (e.g., bones, breast tissue, etc.) of the patient. The resulting image is then an underestimation of the actual image, due to the presence of bone or tissue in the pathway of the emission radiation.

When an image is generated representing the density of the patient, it is possible to compensate for the attenuation effects, since the attenuation of gamma rays

are largely proportional to the density. Such an image can be obtained by sending a known flux of gamma rays from an external source, through the patient at different angles, registering what fraction is transmitted through the patient, and then reconstructing these projections to form an attenuation image (attenuation map). The count density in this image is inversely proportional to the density of the patient and can be used in the reconstruction of the emission image to compensate for gamma ray attenuation.

E. Indications for Use:

The MCD-AC 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 MCD Gamma Camera System by correcting for attenuation effects in the patient.

F. Technological Comparison:

MCD-AC is similar to Vantage in that both devices correct for patient attenuation by use of radioactive sources to create attenuation maps. In both devices, the data is combined from attenuation maps with emission data to correct for attenuation due to bones, tissues, etc. within the patient. The algorithms used to perform this attenuation correction are similar. The reconstruction algorithm used for MCD-AC is the same as the algorithm used for EPIC-MCD with the exception that the MCD-AC algorithm is a modification to the EPIC-MCD algorithm to implement attenuation correction for MCD images.

The source type for the MCD-AC (Cs-137) is different from the source type for the Vantage (Gd-153) because it has been chosen to provide the appropriate attenuation for 511 KeV gamma rays. The source geometry is also different. MCD-AC uses a point source, while Vantage uses a line source. However, when the point source is translated along the patient, the computer views it as a line source.

II. Testing

A study was conducted to demonstrate the single source attenuation correction technique on MCD cameras. Images were obtained using phantoms and humans. The quality of the images produced was similar to the quality of images produced by the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 23 1997

Dennis W. Henkelman, R.A.C.
Director, Regulatory Affairs and Quality Assurance
ADAC Laboratories
540 Alder Drive
Milpitas, CA 95035

Re: K971980
MCD-AC Attenuation Correction
for SPECT Camera
Dated: September 19, 1997
Received: September 22, 1997
Regulatory Class: II
21 CFR 892.1200/Procode: 90 KPS

Dear Mr. Henkelman:

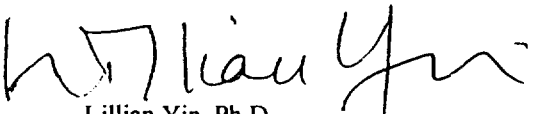
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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

Revised August 8, 1997

510(k) Number (if known): K971980

Device Name: MCD-AC

Sponsor Name: ADAC Laboratories

Indications For Use:

ADAC MCD-AC option to ADAC Dual Head Emission Tomographic System produces images of biodistribution of positron-emitting radioisotopes previously administered to the human body. The system is intended to provide an enhancement to the emission images acquired using the ADAC MCD System by correcting for attenuation effects in the human body.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Clifford C. Stegman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971980

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)