NOV 25 1997

K973233

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: Image Fusion and Review System
Common Name: Gamma Camera Systems
Classification Name: System, Emission Computed Tomography

C. Predicate Device: ADAC Pinnacle^3 Apex

D. Device Description:

The Image Fusion and Review System is an image registration software that is applicable to planar or volumetric images acquired using MCD, SPECT, PET, CT, and MRI modalities. Different image modalities provide complementary information. For example, anatomical imaging modalities like CT and MRI show anatomical features with little regard to function, while functional imaging modalities, such as, MCD, SPECT, etc., show the physiology, blood flow or metabolism. As a result, functional information is difficult to derive from anatomical modalities and anatomical information is hard to identify in functional modalities. Thus, image registration provides a tool to combine information from different modalities to produce a new and more comprehensive image.

E. Indications for Use:

The Image Fusion and Review System is intended to register images geometrically in 3D and display sets of different types of medical images, such as, MCD, SPECT, PET, CT, and MRI, as composite images. It allows the operator to rotate, translate, and align images anatomically, and match the geometric position of the images relative to each other.

F. Technological Comparison:

The display portion of Pinnacle^3 Apex has the same indications for use as the Image Fusion and Review in that both display diagnostic images using such functions as checkerboard, dithered, splash, etc. They utilize the same display algorithms, types of display and operating principle. The display systems differ only in the operator interface, which has been modified for Image Fusion and Review to be consistent with the Pegasys interface.

II. Testing

A study was conducted to demonstrate that information from different modalities could be combined to produce a new and more comprehensive image. The quality of the images produced was similar to the quality of images produced by the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 25 1997

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

Re: K973233
Image Fusion and Review System
Dated: August 26, 1997
Received: August 28, 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: Image Fusion and Review

Sponsor Name: ADAC Laboratories

Indications for Use

The Image Fusion and Review System is intended to register images geometrically in 3D and display sets of different types of medical images such as, MCD, SPECT, PET, CT, and MRI, as composite images. It allows the operator to rotate, translate, and align images anatomically, and match the geometric position of the images relative to each other.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☑
Over-The-Counter Use ☐

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K973233