510(k) SUMMARY OF SAFETY AND EFFECTIVENESS DATA

NOV 26 1997

K973239

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: DICOM 3.0 Software Version 2.0
Common Name: Gamma Camera System
Classification Name: Digital Image Communication System

C. Predicate Device: Cemax Vipstation
AVP PACSPRO 640

D. Device Description:

DICOM 3.0 Software Version 2.0 is a connectivity package software developed according to the ACR-NEMA standard for Digital Imaging and Communication in Medicine (DICOM 3.0). This software converts medical images, such as NM, CT, MRI, or Ultrasound, that are in DICOM 3.0 specified format into Pegasys image format and vice-versa to enable data communication between ADAC Pegasys systems and other medical imaging devices.

Three major operations can be performed with DICOM 3.0 Software Version 2.0 - image data transfer between ADAC systems, data output to DICOM compatible printers, and transfer of image data between ADAC and non-ADAC systems.

E. Indications for Use:

DICOM 3.0 Software Version 2.0 is intended to provide communication and data interchange between multi-modality medical imaging devices, while maintaining the integrity of the image data.

F. Technological Comparison:

DICOM 3.0 Software Version 2.0 and the communication/data interchange portions of the predicate devices have the same indications for use. The operating principles of DICOM 3.0 Software Version 2.0 and the predicate devices are based on ACR-NEMA standard for Digital Imaging and Communication in Medicine (DICOM 3.0), as described in the device description. Communication media, such as, Local Area Network (LAN), Wide Area Network (WAN), and Internet are used to send or receive image data.

II. Testing

Testing was conducted to demonstrate that the software functioned as per its specifications. Import and Export functions were comprehensively tested to ensure that image integrity was maintained. The Print functions were also tested. All tests passed with the actual results matching the expected results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 26 1997

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

Re: K973239
DICOM 3.0 Software Version 2.0
Dated: August 22, 1997
Received: August 28, 1997
Regulatory class: Unclassified
Procode: 90 LMD

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,

William Yin

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): K973239

Device Name: DICOM 3.0 Software Version 2.0

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 G. Hegarty
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K973239