

K974474

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. General Information

FEB 24 1998

- A. Submitted By: ADAC Laboratories
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Tel: (408) 321-9100
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- Contact Person: Dennis Henkelman at address above
- B. Device Trade Name: Pegasys InTouch™
Common Name: Picture Archive and Communication System
(PACS)
Classification Name: Digital Image Communication System
- C. Predicate Device: AVP PACSPRO 640
HyperPACS
AMICAS Web/Intranet Image Server
- D. Device Description:

Pegasys InTouch™ has been developed to provide a physician with the ability to review Pegasys and DICOM images from locations outside the original study area. Pegasys InTouch™ has been designed to operate on standard, off-the-shelf hardware and software components. Using standard WinTel PC systems and the hospital proprietary LAN/WAN (either local or wide area), physicians will have the ability to review and interact with patient data from their desks.

Pegasys and other digital imaging communications systems consist of a computer with a high speed data modem connected to a standard telephone line or computer network that can transmit or receive digitized images. The system is programmed to send, receive, store, copy and display these images in a manner that assures that images are not altered. Operator interface features are also computer controlled so as to enhance the system's capabilities and make the system more user friendly. Images can be displayed with different resolutions and colors; the same image set can be viewed simultaneously at different locations on designated physician workstations.

The physician has the capability to select a variety of display formats for viewing. For example, the physician may select up to 9 separate datasets to be displayed simultaneously, including whole body and snapshot displays; comparative (tomographic) displays of oblique or transverse files; comparative cardiac SPECT data; and SPECT and gated SPECT data in a 10 frame-per-second cine mode. A brief description of the applications available to the physician workstation follows.

1. The physician may select from a number of display formats incorporating from 1 to 9 zones as described previously.
2. *A Tomographic Display* is used to display multiple orientations of the same image set in a comparative manner.
3. The *Cardiac Stress/Rest Comparative* application facilitates the visual comparison of the same cardiac locations during rest and during stress.
4. *Cardiac Comparatives* is similar to the Stress/Rest application above, but displays the stress and rest projections in cine motion.

E. Indications for Use:

Pegasys InTouch™ software is intended to transfer and provide interpretive displays of Pegasys and DICOM image data either compressed or uncompressed to physician workstations via a local area network (LAN) interconnected with Ethernet or via a wide area network (WAN) comprised of two or more LANs in different locations, using a hospital intranet, not the Internet.

F. Technological Comparison:

Pegasys InTouch™ is similar to a wide variety of Picture Archive and Communication Systems (PACS) currently on the market. These systems are designed to send, receive, store, copy and display high resolution digitized images. The images can be digitally scanned into the system or captured from various imaging modalities such as CT and MRI. Each system consists of either a single unit or multiple units networked. Image data is sent from a sending unit through digital network lines or through standard telephone lines by a high speed modem to a receiving station. Once the image is received, it can be stored, copied and displayed. Displayed images may be adjusted for user preference to assist in interpretation.

Pegasys InTouch™ and other currently marketed systems consist of a PC compatible computer with a microprocessor with RAM, monitor, keyboard, mouse/trackball, internal hard drive, modem or Ethernet connection, and Microsoft Internet Explorer 3.0 or Netscape Navigator 3.0.

II. Testing

An image was generated using a prototype of the display applications. The DICOM-format image was downloaded using standard web-based data transfer and displayed into the image viewer. The same image was displayed in each of the four display regions.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 24 1998

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

Re: K974474
Pegasys InTouch™ (PACS)
Dated: November 25, 1997
Received: November 26, 1997
Regulatory class: Unclassified
Procode: 90 LLZ

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): K974474

Device Name: Pegasys InTouch™

Sponsor Name: ADAC Laboratories

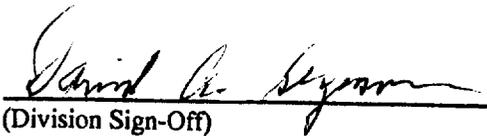
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
Over-The-Counter Use



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

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