

MAR 9 2000

510(k) SUMMARY

K993946

Submitter name: ADAC Laboratories, Inc.
Submitter Address: 540 Alder Drive
Milpitas, CA 95035
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Contact Person: Janice Brown
Date Summary Prepared: February 23, 2000

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510(k) SUMMARY

Device trade name: PEGASYS Ultra

Common name: Nuclear Medicine Imaging Workstation

Classification name: Picture Archiving and Communications System
(per 21CFR section 892.2050)

Predicate Devices: PEGASYS Nuclear Medicine Imaging Computer, K892358

Device Description:

Pegasys Ultra is a UNIX-based SUN display workstation and central processor, a high resolution processing console and TeleLOGIC remote service package. It provides for operator interaction with comprehensive ADAC PEGASYS clinical software provided by ADAC Laboratories and includes On-Line User Documentation.

The workstation allows a qualified operator to process and enhance the data, reconstruct data sets, produce quantitative data from regions of interest, display images, curves and text. Images can be displayed in color, show fluorescence intensity, and different zoom factors. Identification parameters include volume, size, and shape. Use of multiple viewports allows the operator to display images with different color maps, intensities, and zoom factors simultaneously. The PEGASYS desktop contains graphic icons allowing selection of an application such as Renal Analysis, and a menu selection, which consists of a main menu and submenus for image processing of the multiple applications.

Intended Use:

Pegasys Ultra is a nuclear medicine image processing and display workstation that provides software applications used to process, analyze, and display medical images/data. The results obtained may be used as a tool, by a nuclear physician, in determining the diagnosis of patient disease conditions in various organs, tissues, and other anatomical structures. The data processed may be derived from any nuclear medicine procedure. The Pegasys Ultra system should only be operated by qualified healthcare professionals trained in the use of nuclear medicine equipment.

Summary of Technological Characteristics Compared to Predicate Devices:

The predicate device is the "PEGASYS" Nuclear Medicine Imaging Computer, Class II, K892358/A. The FDA determined "PEGASYS" (K892358/A) was substantially equivalent to devices marketed prior to May 28, 1976, the enactment date of the Medical Device Amendments. Both the PEGASYS "Ultra" and the "PEGASYS" Nuclear Medicine Imaging Computer are workstations with SUN UNIX based computers, high resolution graphics and image display consoles for use with ADAC software image processing applications. Both devices use menus and allow the qualified operator to define regions of interest. The PEGASYS "Ultra" software and hardware is more sophisticated, and has progressed with the field of computers and nuclear medicine, but,

the basic algorithms and original calculations have not changed. The functions have been built into the monoliths and protocols in use today, and in conjunction with the upgraded hardware have added speed and an enhanced user interface for the processing of nuclear images, which aid the physician towards a suggestive diagnosis. Additionally, the acquisition software portion has been removed to a separate computer system and is no longer a part of the base Pegasys software.

Summary of Testing

Non-clinical testing was performed for Verification and Validation testing. Testing were completed in compliance with ADAC Laboratories procedures to demonstrate that the Pegasys “Ultra” has met all its specifications, demonstrating substantially equivalent performance to its predicate device, and is safe and effective for its intended use.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 19 2000

Janice E. Brown, RAC
Corporate Director, Regulatory Affairs
ADAC Laboratories
540 Alder Drive
Milpitas, CA 95035

Re: K993946
Pegasys Ultra
Dated: February 23, 2000
Received: February 25, 2000
Regulatory class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Ms. Brown:

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 legally marketed predicate 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) 594-4591. 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" (21CFR 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,



Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

