K040142

FEB - 6 2004

ADMINISTRATIVE INFORMATION

I. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

A. Submitted By:

ADAC Laboratories A Philips Medical Systems Company
540 Alder Drive
Milpitas, California 95035

Tel: (408) 468-3051
Fax: (408) 468-3050

Contact Person: Coleen Coleman
At address above

B. Device Trade Name: ENsphere™ Tempo Cardiology Workstation
Common Name: Picture Archive and Communication Systems (PACS)
Classification Name: Image Processing System

C. Predicate Device(s):

Manufacturer	Product Name	510(k) No.
ADAC Laboratories	Pegasys Ultra™	K993946
ADAC Laboratories	ENsphere™ (Physician Desktop Review)	K021669

D. Device Description:

ENsphere™ Tempo is a Windows®-based Nuclear Medicine workstation specific for the Cardiology market segment. The computer system will consist of a Hewlett Packard XW4100 workstation or equivalent. The comprehensive tools and features provided with this product, will allow the technologist and/or physician to perform image review, processing of source data, post processing, hardcopy production, interpretation, report generation and contains the utilities necessary to support the workflow and data management between those activities. The system will support connectivity aspects necessary to import and export data as required to accomplish daily work scenarios.

E. Intended Use:

ENsphere™ Tempo is a nuclear medicine image processing and display workstation that provides cardiology specific software applications used to

process, analyze, and display medical images. When interpreted by a nuclear physician, the results obtained by using the ENsphere Tempo applications may be used as a tool in determining a patient's diagnosis. ENsphere Tempo should only be operated by qualified healthcare professionals trained in the use of nuclear medicine equipment.

This workstation is intended to be operated in a hospital, clinic, or doctor's office. Patient data may be transferred via DICOM over Local Area Networks (LAN), or Wide Area Networks WAN. The primary users of this product include nuclear medicine technologists who process the data and physicians who display, review, and interpret the processed image data.

F. Technological Comparison:

The ENsphere™ (Physician Desktop Review K021669), Pegasys Ultra™ (K993946), and ENsphere™ Tempo have similar indications for use and overall function and perform in a similar manner with respect to, display, review and processing applications, data storage, and system utilities.

II. CONCLUSION

ENsphere™ Tempo is substantially equivalent to the following predicate devices, Pegasys Ultra™ (K993946) and ENsphere™ (Physician Desktop Review K021669) based on similar intended use, technological comparison, and system performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 6 2004

ADAC Laboratories
% Ms. Ellen Fickewirth
Reviewer
Underwriters Laboratoies, Inc.
Santa Clara Division
1655 Scott Boulevard
SANTA CLARA CA 95050-4169

Re: K040142
Trade/Device Name: ENsphere™ Tempo Cardiology Workstation
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: January 21, 2004
Received: January 22, 2004

Dear Ms. Fickewirth:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510 (k) NUMBER (IF KNOWN): K040142

DEVICE NAME: ENsphere™ Tempo Processing Workstation

SPONSOR NAME: ADAC Laboratories

INDICATIONS FOR USE:

ENsphere™ Tempo is a nuclear medicine image processing and display workstation that provides cardiology specific software applications used to process, analyze, and display medical images. The applications included with ENsphere Tempo may be used as a tool, by the Physician in interpreting Nuclear Cardiology procedures. ENsphere Tempo should only be operated by qualified healthcare professionals trained in the use of nuclear medicine equipment.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040142