K080961

ADMINISTRATIVE INFORMATION

I. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

A. Submitted By:

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Contact Person: Lori R. Peterson
At address above

B. Device Trade Name: NM Application Suite
Common Name: Image Processing System
Classification Name: Picture Archive and Communication Systems (PACS)

C. Predicate Device(s):

Manufacturer	Product Name	510(k) No.
ADAC Laboratories	Pegasys Ultra™	K993946
ADAC Laboratories	JETStream® Workspace	K061029

D. Device Description:

The NM Application Suite is a Windows®-based Nuclear Medicine suite of image display and processing applications for the Nuclear Medicine market segment. The software package is deployable on hardware platforms, which meet the minimum requirements needed to run the software. The NM Application Suite includes both review and processing functionality and can be segmented into separate review and analysis configurations, such as a Planar and SPECT. 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:

A nuclear medicine image display and processing application suite 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 gamma camera. The NM Application Suite should only be operated by qualified healthcare professionals trained in the use of nuclear medicine equipment.

F. Technological Comparison:

The Pegasys Ultra™ (K993946), JETStream® Workspace (K061029) and the NM Application Suite have similar indications for use and overall function and perform in a similar manner with respect to, display, review and processing applications.

II. CONCLUSION

The NM Application Suite is substantially equivalent to the following predicate devices, Pegasys Ultra™ (K993946) and JETStream® Workspace (K061029) 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

APR 18 2008

Philips Medical Systems (Cleveland), Inc.
% Mr. Morten Simon Christensen
Staff Engineer & FDA Accredited Person Program
Underwriters Laboratories, Inc.
455 E. Trimble Road
SAN JOSE CA 95131-1230

Re: K080961
Trade/Device Name: NM Application Suite
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 2, 2008
Received: April 4, 2008

Dear Mr. Christensen:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

510(k) Number (if known): K080961

Device Name: NM Application Suite

Indications For Use:

A nuclear medicine image display and processing application suite 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 gamma camera. The NM Application Suite should only be operated by qualified healthcare professionals trained in the use of nuclear medicine equipment.

Prescription Use __X___ (Part 21 CFR 801 Subpart D) OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K080961