ADMINISTRATIVE INFORMATION

MAY 2 4 2011

I. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

A. Submitted By:

Philips Medical Systems (Cleveland), Inc.
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Contact Person: Lori R. Peterson
At address above

Date Prepared: February 3, 2011

B. Device Trade Name: EBW NM 2.0
Common Name: Image Processing System
Classification Name: Picture Archive and Communication Systems (PACS)

C. Predicate Device(s):

Manufacturer	Product Name	510(k) No.
Philips Medical Systems (Cleveland), Inc.	NM Application Suite	K080961
Philips Medical Systems (Cleveland), Inc.	AutoSPECT	K090403

D. Device Description:

EBW NM 2.0 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 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.

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 structure. The data processed may be derived from any nuclear medicine camera. EBW NM 2.0 should only be operated by qualified healthcare professionals trained in the use of nuclear medicine equipment.

F. Technological Comparison:

The predicate, NM Application Suite (K080961) and EBW NM 2.0 have similar indications for use and overall function and perform in a similar manner with respect to, display, review and processing applications. AutoSPECT (K090403) and the Philips reconstruction applications (AutoSPECT Pro), that are a subset of the EBW NM base package, have similar indications for use and overall function and perform in a similar manner with respect to reconstruction processing, which includes resolution recovery, scatter correction, noise control, and attenuation correction.

II. CONCLUSION

The EBW NM 2.0 is substantially equivalent to the NM Application Suite (K080961) a predicate device based on similar intended use, technological comparison, and system performance. The subset of applications, AutoSPECT Pro, is substantially equivalent to the AutoSPECT predicate device (K090403) based on similar intended use and technological comparison.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Philips Medical Systems (Cleveland), Inc.
% Mr. Ned Devine
Senior Staff Engineer
Underwriters Laboratories, Inc.
333 Pfingsten Road
NORTHBROOK IL 60062

MAY 24 2011

Re: K111336
Trade/Device Name: EBW NM 2.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 10, 2011
Received: May 12, 2011

Dear Mr. Devine:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K111336

Device Name: EBW NM 2.0

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 structure. The data processed may be derived from any nuclear medicine camera. EBW NM 2.0 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) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K111336