K061685
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510(k) Summary

The following information is being submitted in accordance with the requirements of 21 CFR 807.92.

Company name: Philips Medical System North America Company
Address: 22100 Bothell Everett Highway
Bothell, WA 98021-8431

SEP 15 2006

Registration No: 1217116

Contact Person: Lynn Harmer
Telephone No.: 425-487-7312

Date prepared: 16 May 2006

Device (Trade Name): 3D-RX Option for BV Pulsera, Release 2.2

Regulation Name: Mobile x-ray system

Regulation No.: 21 CFR 892.1720

Regulatory Class: II

Product Code: 90 IZL

Manufacturer: Philips Medical Systems Nederland B.V.
Veenpluis 4-6
5684 PC Best, The Nederlands

Predicate Device:
The Philips 3D-RX Option for BV Pulsera is substantially equivalent to the Siemens ArcadisOrbic 3D (FDA Number K042646).

Device Description:
The Philips 3D-RX Option for BV Pulsera is a mobile C-Arm X-Ray System offering Radiographic and Fluoroscopic techniques, which extends the functionality of the BV Pulsera Release 2.2 with 3D imaging. Using the 3D-RX Option on the BV Pulsera, an operator performs a rotation run to acquire images. These images are used by an integrated 3D workstation which creates a 3D reconstruction, and which provides tools for further processing and analysis. Both hardware and software additions are added to the BV Pulsera C-Arm X-Ray System to produce the 3D-RX Option.

Indications for Use:
The BV Pulsera system is used for radiological guidance and visualization during diagnostic, interventional and surgical procedures on all patients except babies, within the limits of the systems. The system is to be used in health care facilities both inside and outside the operating room, sterile as well as non-sterile environments, with a variety of procedures.

The 3D-RX functionality on the BV Pulsera provides 3D imaging and intended to be used whenever the physician benefits from intra-operatively-generated 3D information of high-contrast objects and anatomical structures.

The 3D application areas for the BV Pulsera are:

- *Skull (Ear Nose and Throat, Maxillo Facial)*
- *Cervical spine*
- *Fore arm*
- *Elbow*
- *Hand /Wrist*
- *Knee*
- *Lower leg*
- *Foot / Ankle*

General Safety and Effectiveness:
The device and its labeling will comply with the applicable requirements of the federal performance standards (Code of Federal Regulations, Title 21, subchapter J-Radiological Health, parts 1020.10 and 1040.10).

The device will comply with applicable requirements of the Underwriters Laboratories Standard for Safety-UL 60601-1. All required documents and reports have been or will be submitted to the appropriate oversight agency to establish compliance with the applicable requirements.

Conclusion

The 3D-RX Option for BV Pulsera release 2.2 does not introduce new potential hazards. Philips Medical Systems considers the 3D-RX Option for BV Pulsera release 2.2 substantially equivalent with the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP 15 2006

Philips Medical Systems North America
c/o Ms. Michelle S. Lee
Senior Project Engineer/Reviewer
UL Conformity Assessment Services
Underwriters Laboratories, Inc.®
2600 N. W. Lake Road
CAMAS WA 98607-8542

Re: K061685
Trade/Device Name: 3D-RX Option for BV Pulsera
Regulation Number: 21 CFR §892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: IZL
Dated: August 25, 2006
Received: August 28, 2006

Dear Ms. Lee:

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 (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 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 this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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 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): K061685

Device Name: 3D-RX Option for BV Pulsera

Indications For Use:

The "3D-RX" Option on the BV Pulsera provides 3D imaging functionality and is intended to be used whenever the physician benefits from intra-operatively-generated 3D information of high contrast objects and anatomical structures.

Prescription Use Yes (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use No (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)

Carolyn A Neuland for N C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061685