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TRANSAMERICAN
Medical Imaging

K092713

510(k) Summary

JUL 16 2010

I. General Information

Submitter: TransAmerican Medical Imaging
965 West 325 North
Lindon, UT 84042
USA

Contact Person: Robert H. Woodward
President

Summary Preparation Date: January 12, 2009

II. Names

Predicate Device Name: Standard Footswitch or Hand Switch (common name and classification name)

Substantially Equivalent Device Name: Spectre Wireless Encrypted Footswitch and Hand switch System

Primary Classification Name: Accessory for:

- System, X-Ray, Stationary
- System X-ray, Mobile
- Angiographic X-ray system
- Image-intensified Fluoroscopic X-ray System
- Non-image-intensified Fluoroscopic X-ray System

III. Predicate Devices:

Philips Medical Systems Standard Footswitch—Accessory for:

- V Series Angiographic system (K973482)
- H Series Cardiographic System (K971365)
- FD Series Cath/Angio System (K041949)
- Mobile C-arm System (K010762)
- R&F System (K032046)

GE/OEC Medical Systems Standard Footswitch—Accessory for:

- OEC 9800 Mobile C-Arm System (K024012)
- OEC 9900 Mobile C-Arm System (K073543)

IV. Product Description:

The predicate device in this submission is an accessory to the main predicate devices listed, and is covered under those device registrations. Individual device listings for the accessory footswitch and hand switches were not found for the predicate devices listed. One wireless footswitch classification was found in an unrelated but parallel classification. That was the Iridex Wireless Footswitch (K062074) for ophthalmic lasers, Classification Product Code HQF, Regulation number 886.4390.

The common footswitch or hand switch of the predicate device is comprised of a set of switches connected to a base that send signals through a cable to the main x-ray generator. Signals sent typically are fluoroscopy or x-ray exposure commands, or other simplified configuration commands such as lights on or off, last image hold, etc. These signals are simple "on/off" analog signals, usually less than 24 VDC, and are interpreted by the predicate device to perform its function. The disadvantage to the common footswitch or hand switch is the cable that attaches them to the predicate device. These cables become a trip hazard to personnel because they lay on the floor or on other spaces. They are also a contamination hazard and are difficult to clean. Because these cables are flexed continually, cable breakage is common, creating maintenance and equipment performance problems.

The Spectre System is an alternate option to the existing cabled foot switch and hand switch for users of X-ray systems. It consists of three parts—a footswitch/transmitter, a hands switch/transmitter, and a receiver. The Spectre system receiver connects to the x-ray system through the same connector as the current footswitch, and operates the x-ray system by exactly emulating the functionality of the current cabled footswitch and hand switch. There are no cables, therefore, no trip hazards, contamination hazards, or cable breakage hazards. The footswitch and hand switch are powered by batteries, eliminating shock hazards. The receiver is mounted on the predicate device, and is powered from the predicate device.

V. Indications for Use:

The Spectre System is intended for use with compatible diagnostic x-ray systems in hospital or outpatient facilities. The Spectre System is indicated for use as an accessory to provide input control to compatible x-ray systems. This accessory includes a wireless footswitch, a hand switch, and a receiver. It is cleared for use only for the particular indications of the X-ray system to which it is attached. Attachment to any other device other than the predicate device it is designed for may result in damage to the Spectre system or to the connected device.

VI. Rationale for Substantial Equivalence

Non clinical testing in our facility included the installation of the Spectre system onto the predicate devices listed, and conducting functional testing of the Spectre system to insure exact functional performance as compared to the predicate footswitch and hand switches. Test results showed in each individual condition that the Spectre system performed identically to the predicate devices. 100 iterations of each possible signal configuration were tested. There were no malfunctions noted during the tests. Long term testing using the Spectre system over a period of weeks also produced reliable functionality results from the system. During these tests, no malfunction was recorded.
The Spectre System shares the same indications for use, device operation, and overall technical and functional capabilities of all cabled footswitches and hand switches used by the predicate devices. It is therefore substantially equivalent to the predicate devices.

VII. Safety and Effectiveness Information

The purpose for using the Spectre wireless encrypted Footswitch and Hand Switch System is to increase the safety of patients by eliminating the contamination hazards of cables as well as improving the overall performance record of the predicate device, thus making it a safer device by eliminating the cables. This system also increases the safety and efficiency of the medical personnel by allowing the cable free "trip free" workspace provided by the wireless system.
Non clinical functional testing showed complete functionality of the system without error. Significant studies done by independent sources (shown in section 18) have demonstrated the safety, efficiency and reliability of wireless systems in the medical environment. All components are UL listed for Medical use, and are therefore tested and demonstrated to be as safe in the medical environment as the predicate devise. The review of the indications for use and technical characteristics provided demonstrates that the Spectre system is substantially equivalent to the predicate devices.

VIII. Conformance to Standards

All design, testing, manufacturing and documentation was performed in conformance with IEC 60601-1, Medical Electrical Equipment-Part 1: General Requirements for Safety, 1988; amendment 1, 1991-11; amendment 2, 1995 (General). Independent testing was conducted by Underwriter's Laboratories, Inc. for compliance to the above mentioned standard. The complete report is included in section 18 of this submission. These tests concluded that this system complies and conforms to all applicable sections of this standard.

Additional testing by an independent Laboratory demonstrates compliance to the following standards: IEC 60601-1-2 Medical Device (ed 2.1) (2004) which includes IEC 61000-4-2(ed 1.2) 2001, IEC 61000-4-3 (ed 3) 2006, IEC 61000-4-4(ed 2) 2004, IEC 61000-4-5(ed 1.1) 2001, IEC 61000-4-6(ed 2) 2003, and IEC 61000-4-11(ed 2) 2004. Also included in that testing was compliance to EN Emissions Class B for Radiated Emissions(1998) and Conducted Emissions (1998). The complete testing is found in section 18. These tests concluded that the Spectre System is in conformance to FCC Standards, and all applicable sections of IEC 60606-1-1-2 Medical Device (ed 2.1) 2004.

IX. Conclusion

The Spectre System was designed and manufactured to be a replacement for the cabled devices used with the predicate devices. Internal testing shows it performs the exact same tasks, but simply uses proven new technologies to eliminate the need for hazardous cabling. It is substantially equivalent to the predicate devices in similar indications of use, similar design and functional features with, and thus is substantially equivalent to, the predicate devices. Independent testing confirms conformance to all applicable standards.

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

TransAmerica Medical Imaging
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Senior Staff Engineer
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JUL 13 2010

Re: K092713
Trade/Device Name: Spectre Wireless Encrypted Footswitch and Hand switch System
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: IZL
Dated: March 12, 2010
Received: March 16, 2010

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,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K092713

Device Name: Spectre Wireless Encrypted Footswitch and Hand switch System

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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 OF NEEDED)

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ OIVD

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K092713