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MAR - 2 2011

Abbreviated 510(k) Notification

510(k): Spaulding Clinical IQ Electrocardiograph Device Summary

Submitter:

Date: February 14, 2011

Paul Schultz, VP of Quality Assurance
Spaulding Clinical Research, LLC
525 South Silverbrook Drive
West Bend, WI 53095

FAX: (262) 334-6067
Phone: (262) 334-6020
Contact: Paul Schultz (see above)

Trade Name: IQ Electrocardiograph
Common Name: Electrocardiograph
Classification Name: Electrocardiograph
(Per 21 CFR 870.2340)

Legally marketed devices to which S.E. is claimed:

The Spaulding Clinical Research IQ Electrocardiograph is substantially equivalent to the legally marketed devices presently in distribution:

- Mortara Instrument ELI PC Electrocardiograph (K093339)
- Corscience GmbH & Co.KG, Corscience BT PC ECG Device (K082077)

Description:

The proposed Spaulding IQ is an electrocardiograph that combines proprietary hardware, current industry technologies and an off-the-shelf personal computer to achieve a highly reliable electrocardiograph. The IQ is a standard 12-lead non-interpretive electrocardiograph system that is indicated for use by qualified medical professionals in a clinical setting. The IQ combines proprietary hardware and an off-the-shelf personal computer. The concept behind the IQ is to provide the user with an ECG acquisition module that can also transfer the acquired ECG record to a participating PC. The PC side of the system will employ installed proprietary software applications to receive the record and process it for display, printing and storage, or further processing. The device may be used in medical clinics and offices of any size, to include Clinical Research Organizations.

The system will be based on two major components:

- An ECG acquisition module that can (1), acquire the patient demographics by means of an incorporated voice signal input component that uses current industry voice recognition technology and (2) acquire a patient 12-lead ECG. The patient ECG and voice signal data will be stored on the module in local memory and subsequently transferred to a PC Station via a standard USB connection.

- Proprietary Software Application(s) (Mason Protocol) installed on a participating networked PC, that will receive the ECG data from the Acquisition Module and will communicate bi-directionally to the Clinical Server (CTS) and gather/transmit information about the patient's demographics, visit information as well as acquired ECG data. The application controls user access and authentication, submits the resulting ECG and demographic and visit information to the Clinical Server and allows the user to select the appropriate visit protocol and enter patient's demographic and visit data.

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The acquisition module (AM) requires use of supplied proprietary Spaulding 10-wire ECG patient cable for patient connection. The cable is unique to the AM, can only be used with the AM, and is distributed as a device component with the AM.

The PC host interface is made using a standard off-the-shelf USB RS232 cable. The USB connection is used to transfer data from the AM to the PC host. The Mason Protocol Software is installed, configured and managed via a web-based user interface, and the interface supports a variety of roles. Each role encapsulates varying degrees of application authorization. The central application can provide data through the web interface, or through various data exports. Interaction with the site and reader applications is accomplished via secured web service interfaces using the HTTPS protocol.

Intended Use:
The intended purpose of the IQ Electrocardiograph system is to collect and transfer resting Electrocardiograms from patients to a host participating PC. The complete system includes an Acquisition Module (AM) with patient applied part, an off-the shelf USB cable, and the PC Application Mason Protocol to connect bi-directionally to the Clinical Information Management Server (CIMS) and gather/transmit information about the patient's demographics, visit information as well as acquired ECG data. The AM part of the device will be used in a medically equipped room in a patient environment, and will be in direct contact with the patient during acquisition. The patient will be disconnected during patient data transfer. The Mason Protocol software may be installed in an office computer in a normal room.

The patient population for which the device will be used may be healthy or diseased of any age. Patients will usually be ambulatory, however-the patient will be in a supine position for EGG acquisition. Operators of the device will be medical doctors or qualified ECG technicians. The device is intended to be used frequently, in normal office hours and in normal lighting conditions.

Indications for Use:
The proposed Spaulding Electrocardiograph is a non-invasive prescription device.

- The IQ device is indicated for use to acquire, analyze, display and print electrocardiograms.
- The device is indicated for use for pediatric and adult populations, diseased or non-diseased. The device is not indicated for use for neonatal (birth to 28 days) or infants (29 days up to 2 years).
- The device is indicated for use to provide data for consideration by a physician. The interpretations of EGG's are only significant when used in conjunction with a physician over-read as well as consideration of all other relevant patient data.
- The device is indicated for use in a clinical setting, by qualified medical professionals, properly trained for EGG monitoring and use of the system. The personnel must be experienced in cardiovascular problematic situations and emergency procedures or pathologies related to cardiac involvements, It is not intended as a sole means of diagnosis.
- The device is not intended to be used as a vital signs physiological monitor.
- It is not designed for out of hospital transport.
- It is not designed for use in highly invasive environments, such as an operating theatre.
- The cardiac data and analysis provided is reviewed, confirmed, and used by trained medical personnel in the diagnosis of patients with various rhythm patterns.

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

MAR - 2 2011

Spaulding Clinical Research, LLC
c/o Mr. Paul Schultz
Vice President of Quality Assurance
525 S. Silverbrook Drive
West Bend, WI 53095

Re: K110065
Trade/Device Name: Spaulding Clinical Research IQ Electrocardiograph
Regulatory Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: II (two)
Product Code: 74 DPS
Dated: January 7, 2011
Received: January 10, 2011

Dear Mr. Schultz:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K110065

Indications for Use

510(k) Number (if known): K110065

Device Name: **Spaulding Clinical Research IQ Electrocardiograph**

Indications for Use:

The IQ Electrocardiograph is a non-invasive prescription device that is indicated for use:

- The proposed IQ Electrocardiograph is indicated for use to acquire, analyze, display and print electrocardiograms.
- The device is indicated for use for pediatric and adult populations, diseased or non-diseased. The device is not indicated for use for neonatal (birth to 28 days) or infants (29 days up to 2 years).
- The interpretations of ECG data offered by the device are only significant when used in conjunction with a physician over-read as well as consideration of all other relevant patient data.
- The device is indicated for use in a clinical setting, by qualified medical professionals, properly trained for ECG monitoring and use of the system. The personnel must be experienced in cardiovascular problematic situations and emergency procedures or pathologies related to cardiac involvements. It is not intended as a sole means of diagnosis.
- The device is not intended to be used as a vital signs physiological monitor.
- It is not designed for out of hospital transport.
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- The cardiac data and analysis provided is reviewed, confirmed, and used by trained medical personnel in the diagnosis of patients with various rhythm patterns.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart D) (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)

for B Zuckerman

(Division Sign-Off) 3/2/2011

Division of Cardiovascular Devices

510(k) Number K110065