DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 12, 2015

Spaulding Clinical Research, LLC
Mr. Andre Leak
Manager of Regulatory Affairs
525 South Silverbrook Drive
West Bend, Wisconsin 53095

Re: K150564
Trade/Device Name: Spaulding Electrocardiograph 2100iQ
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: July 10, 2015
Received: July 13, 2015

Dear Mr. Leak:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Kenneth J. Cavanaugh -S

for

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

Enclosure

Indications for Use

510(k) Number (if known): K150564

Device Name: **Spaulding Electrocardiograph 2100iQ**

Indications for Use:

The Spaulding Electrocardiograph is intended to acquire a resting, diagnostic 12-lead ECG for display and subsequent upload to a Medical Device Data System (MDDS). This enables clinicians, or trained care personnel who are acting on the orders of a licensed physician, to acquire, process, display, store, and print diagnostic 12 lead ECGs.

The Spaulding Electrocardiograph is for use on adult and pediatric populations, diseased or non-diseased and is not intended for use on neonatal (birth to 28 days) or infants (29 days up to 2 years). The device is not for use in highly invasive environments, or as a vital signs physiological monitor.

The Spaulding Electrocardiograph provides un-interpreted 12-lead ECG data and is not to be a sole means of diagnosis.

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)

spaulding clinical
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Spaulding Electrocardiograph 510(k) Summary

Submitter: **Date: July 6, 2015**

Andre Leak, Manager of Regulatory Affairs

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Trade Name: Spaulding Electrocardiograph 2100iQ
Common Name: Electrocardiograph
Classification Name: Electrocardiograph
(Per 21 CFR 870.2340)

Legally marketed device to which Substantial Equivalence is claimed:

The Spaulding Electrocardiograph 2100iQ is substantially equivalent to the legally marketed device presently in distribution:

- Spaulding IQ Electrocardiograph (K110065)

Description:

The Spaulding Electrocardiograph Model 2100iQ works with the Spaulding webECG Diagnostic ECG management solution. (Medical Device Data System) The light weight and portable Spaulding Electrocardiograph 2100iQ device collects and uploads a dedicated patient's ECG (electrocardiograph) information to the WebECG system and receives a report back from the WebECG system.

The Spaulding Electrocardiograph 2100iQ streams ECG heart rhythm data to a iOS® mobile device using Bluetooth® wireless communication. Using the Spaulding Patient Cable and strategically placed electrodes, it allows the Spaulding Clinical Client Application software (Spaulding ECG) to collect a 12-lead ECG.

The Spaulding ECG application then communicates to the Spaulding webECG server to upload ECG data through an Internet connection.

Intended use:
The Spaulding Electrocardiograph is intended to acquire a resting, diagnostic 12-lead ECG for display and subsequent upload to a Medical Device Data System (MDDS). This enables clinicians, or trained care personnel who are acting on the orders of a licensed physician, to acquire, process, display, store, and print diagnostic 12 lead ECGs.

The Spaulding Electrocardiograph is for use on adult and pediatric populations, diseased or non-diseased and is not intended for use on neonatal (birth to 28 days) or infants (29 days up to 2 years). The device is not for use in highly invasive environments, or as a vital signs physiological monitor.

The Spaulding Electrocardiograph provides un-interpreted 12-lead ECG data and is not to be a sole means of diagnosis.

Technical Comparison to predicate:

The Spaulding Electrocardiograph 2100iQ is the next version of the Spaulding IQ Electrocardiograph predicate device. Most design features, and technical components are shared between the two devices. The development of the Spaulding Electrocardiograph 2100iQ used the Spaulding IQ Electrocardiograph predicate as the base design and all added improvements / modifications / features were made using the base design. The hardware for ECG acquisition has not changed from the predicate device.

Feature	Predicate Spaulding IQ Electrocardiograph	Spaulding Electrocardiograph 2100iQ	Comparison Summary
Patient Cable	Proprietary 12-Lead Patient Cable	Proprietary 12-Lead Patient Cable	Same – The Spaulding Electrocardiograph 2100iQ uses the same patient cable as the predicate Spaulding IQ Electrocardiograph
Electrocardiograph	Round shape, single button, portable, LED display	Round shape, single button, portable, LED display	Same – The Spaulding Electrocardiograph 2100iQ uses the same casing, circuit board, LED display as the predicate Spaulding IQ Electrocardiograph device.
Leads	12-Lead	12-lead	Same - The Spaulding Electrocardiograph 2100iQ is a 12-lead electrocardiograph the same as the predicate Spaulding IQ Electrocardiograph.
Circuit Board	Cased in Printed Circuit Board	Cased in Printed Circuit Board	Same – The Spaulding Electrocardiograph 2100iQ uses the same printed circuit board component as the predicate Spaulding IQ Electrocardiograph.
Daughter Board	None	Daughter board contains Bluetooth® Chip and Apple Coprocessor.	**Different** – The Spaulding Electrocardiograph has an additional daughter circuit board affixed which contains the Bluetooth® radio and Apple coprocessor.
Microcontroller	AVR 8 bit Microcontroller	AVR 8 bit Microcontroller	Same – The Spaulding Electrocardiograph 2100iQ uses the same microcontroller component as the predicate Spaulding IQ Electrocardiograph.
Battery	Device is powered by an internal polymer lithium ion 3.7V rechargeable battery.	Device is powered by an internal polymer lithium ion 3.7V rechargeable battery.	Same – The Spaulding Electrocardiograph 2100iQ uses the same battery as the predicate Spaulding IQ Electrocardiograph device.

ECG Waveform Acquisition	Electrodes to patient cable to electrocardiograph	Electrodes to patient cable to electrocardiograph	Same – The Spaulding 2100iQ acquires signal from electrodes thru the patient cable to the electrocardiograph the same way as the predicate Spaulding IQ electrocardiograph.
ECG Data Transfer	Data Transfer via standard USB Cable	Data Transfer via Bluetooth® Technology	**Different** – The Spaulding Electrocardiograph 2100iQ transfers data wirelessly to the receiving client application software. The predicate Spaulding IQ Electrocardiograph transfers data via USB cable to the client application software.
Software Component	Spaulding Client Application Software	Spaulding Client Application Software	Same – The Spaulding Electrocardiograph 2100iQ requires the use of the Spaulding Client Application Software running on a computer/display device, which is also required with the predicate Spaulding IQ Electrocardiograph.
Client Software platform	Personal Computer	Mobile device	**Different** – The Spaulding Electrocardiograph 2100iQ interfaces with the Spaulding Client Application Software running on a Mobile Device. The predicate Spaulding IQ Electrocardiograph interfaces with the Spaulding Client Application Software running on a personal computer.
ECG Interpretation	No	No	Same – The Spaulding Electrocardiograph 2100iQ provides un-interpreted ECG data the same as the predicate Spaulding IQ Electrocardiograph.
ECG Display	ECG data display occurs on personal computer screen after acquisition and data upload using Spaulding Client Application software	ECG data is displayed on mobile screen in real-time before, during, and after acquisition. Acquired ECG displayed before and after upload.	**Different** – The Spaulding Electrocardiograph 2100iQ streams data to the Spaulding Client Application Software. The software allows the data to be displayed as it is received, it will also allow user to see the acquired ECG data before or after upload. The predicate Spaulding IQ Electrocardiograph only allows the Spaulding Client Application software to display the ECG data after acquisition and upload.

Pacemaker Interaction	Has ability to acquire ECG data in the presence of pacemaker pulses.	Has ability to acquire ECG data in the presence of pacemaker pulses and identify that a pacemaker pulse is present.	**Different** – The Spaulding Electrocardiograph 2100iQ, in conjunction with the Spaulding Client Application software, has the additional ability to give a visual notification on the computing/display device when a pacemaker pulse is detected.
Internet access	Internet access is required for ECG data upload and retrieval.	Internet access is required for ECG data upload and retrieval.	Same – The Spaulding Electrocardiograph 2100iQ requires internet access to upload and retrieve data from an MDDS, the same as the predicate Spaulding IQ electrocardiograph device.
Device Charging	Device battery is charged by USB connection to personal computer or medical grade USB charger.	Device battery is charged by USB connection to personal computer or medical grade USB charger.	Same – The Spaulding Electrocardiograph 2100iQ uses the same charging method as the predicate Spaulding IQ Electrocardiograph device.
Materials			
Patient Cable	Elastolan	Elastolan	Same – The Spaulding Electrocardiograph 2100iQ uses the same patient cable as the predicate Spaulding IQ Electrocardiograph device.
Device enclosure (plastic casing)	ABS Polycarbonate	ABS Polycarbonate	Same – The Spaulding Electrocardiograph 2100iQ device enclosure is the same device enclosure as the predicate Spaulding IQ Electrocardiograph device.
Software & Settings Comparison			
Lead Markers	Spaulding Client Application Software displays lead markers	Spaulding Client Application Software displays lead markers	Same – The Spaulding Client Application software used in conjunction with the Spaulding Electrocardiograph 2100iQ can be configured to display lead markers the same as the predicate Spaulding IQ Electrocardiograph device.
Sensitivity, mm/mV (Gain)	2.5,5,10,20,40	2.5,5,10,20,40	Same – The Spaulding Electrocardiograph 2100iQ has the same gain options as the predicate Spaulding IQ Electrocardiograph device.

Chart Speed, mm/s	5,10,12.5,25,50	5,10,12.5,25,50	Same – The Spaulding Electrocardiograph 2100iQ has the same chart speeds as the predicate Spaulding IQ Electrocardiograph device.
ECG display formats	User Selectable 12-lead, 3+1, 3+3	User Selectable 12-lead, 12x1, 6x1, 4x1, 3x1, 2x1, 1x1, 6x2, 4x2, 3x2, 2x2, 1x2	**Different** – The Spaulding Electrocardiograph 2100iQ allows for ECGs to be displayed in a wider range of display formats than the predicate Spaulding IQ Electrocardiograph device.
Safety / Standards Comparison			
Performance	AAMI EC11:1991/2001/2007 Diagnostic Electrocardiograph Devices IEC 60601-2-51:2003 Medical Electrical Equipment - Particular requirements for the safety, including essential performance, of recording and analyzing single channel and multichannel electrocardiographs.	IEC 60601-2-25:2011 Particular requirements for the basic safety and essential performance of electrocardiographs.	Equivalent – The Spaulding Electrocardiograph 2100iQ essential performance is comparable to performance compliance of the predicate Spaulding IQ Electrocardiograph.
Biocompatibility Safety	ISO 10993 Part 1, Part 5, Part 10	ISO 10993 Part 1, Part 5, Part 10	Same – The Spaulding Electrocardiograph 2100iQ uses the same patient cable and the same device enclosure of the predicate Spaulding IQ Electrocardiograph device.
Environmental Safety	IEC 60601-2-25:2011 Particular requirements for the safety of electrocardiographs	ISO 60601-1:2005 ed 3.1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60601-2-25:2011 Particular	**Different** – The Spaulding Electrocardiograph 2100iQ has been tested in a wider range of environmental conditions than the predicate Spaulding IQ Electrocardiograph device. The Spaulding Electrocardiograph 2100iQ can be used in transit settings as a portable device.

		requirements for the basic safety and essential performance of electrocardiographs.	
Water ingress and particulate matter rating	IEC 60529:2001 Degrees of protection provided by enclosures IPX21	IEC 60529: 2013 Degrees of protection provided by enclosures IP22	**Different** – The Spaulding Electrocardiograph 2100iQ has been tested and complies with a higher water ingress and particulate matter rating than the predicate Spaulding IQ Electrocardiograph device.
Thermal safety	IEC 60601-2-25:2011 Particular requirements for the safety of electrocardiographs	ISO 60601-1:2005 ed 3.1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60601-2-25:2011 Particular requirements for the basic safety and essential performance of electrocardiographs.	**Equivalent** – The Spaulding Electrocardiograph 2100iQ has been tested in a wider range of temperature conditions than the predicate Spaulding IQ Electrocardiograph device. The Spaulding Electrocardiograph 2100iQ extends use temperatures to those found in home settings and transit settings as a portable device.
Electrical Safety	ISO 60601-1 ed 2.0	ISO 60601-1:2005 ed 3.1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60601-2-25:2011 Particular requirements for the basic safety and essential performance of electrocardiographs.	**Equivalent** – The Spaulding Electrocardiograph 2100iQ has been tested in a wider range of electrical tests than the predicate Spaulding IQ Electrocardiograph device. It complies with the current 60601-1 ed 3.0. The Spaulding Electrocardiograph 2100iQ extends use environments to home settings and transit settings as a portable device.

Applied Part Classification	TYPE CF	TYPE CF	Same – The Spaulding Electrocardiograph 2100iQ's applied part classification is the same as the predicate Spaulding IQ Electrocardiograph device applied part classification.
Patient Cable Safety	21 CFR Part 898.12 Lead Sets	21 CFR Part 898.12 Performance standard for electrode and lead wire sets AAMI/ANSI EC53:2013 ECG Trunk Cables and Patient Leadwires	Same – The Spaulding Electrocardiograph 2100iQ patient cable performance testing completed is the same and more extensive as the predicate Spaulding IQ Electrocardiograph device.
Mechanical Safety	IEC 60601-2-25:2011 Particular requirements for the safety of electrocardiographs	ISO 60601-1:2005 ed 3.1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60601-2-25:2011 Particular requirements for the basic safety and essential performance of electrocardiographs.	**Equivalent** – The Spaulding Electrocardiograph 2100iQ has been tested in a wider range of impact and vibration tests than the predicate Spaulding IQ Electrocardiograph device. The Spaulding Electrocardiograph 2100iQ extends use environments to home settings and transit settings as a portable device.
EMC safety	ISO 60601-1-2:2001-09 Medical Electrical Equipment – Part 1: General requirements for safety Subpart 2:Collateral standard: Electromagnetic Compatibility – Requirements and tests	IEC 60601-1-2:2007 ED. 3.0 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests Class B	**Different** – The Spaulding Electrocardiograph 2100iQ has been tested for electromagnetic disturbances the same as the predicate Spaulding IQ Electrocardiograph device, however the Spaulding Electrocardiograph 2100iQ can be used in transit settings as a portable device.

Chemical safety	Not Applicable – The Spaulding IQ Electrocardiograph is not designed to be used with or contain hazardous chemicals.	Not Applicable – The Spaulding Electrocardiograph 2100iq is not designed to be used with or contain hazardous chemicals.	Same – The Spaulding Electrocardiograph 2100iQ does not contain and is not to be used with hazardous chemicals which is the same as the predicate Spaulding IQ Electrocardiograph.
Radiation safety	Not Applicable – The Spaulding IQ Electrocardiograph does not emit radiation.	Not Applicable – The Spaulding Electrocardiograph 2100iq does not emit radiation	Same – The Spaulding Electrocardiograph 2100iQ does not emit radiation same as the predicate Spaulding IQ Electrocardiograph device.
Sterility	Not Applicable – The Spaulding IQ Electrocardiograph is not provided sterile.	Not Applicable – The Spaulding Electrocardiograph 2100iq is not provided sterile.	Same – The Spaulding Electrocardiograph 2100iQ is not designed to be provided sterile same as the predicate Spaulding IQ Electrocardiograph device.

A comparison test between the Spaulding Electrocardiograph 2100iQ and the predicate was completed. Wireless transmission functionality (via Bluetooth) performance testing compared the data captured from the predicate Spaulding IQ Electrocardiograph 1000, against the data captured from the Spaulding Electrocardiograph 2100iQ utilizing a calibrated simulator with arrhythmia capabilities for both devices. The results from the acquired and transferred data was compared to ensure there was no discrepancy. Tests were performed with varying beats per minute, ventricular tachycardia and ventricular fibrillation conditions. The Spaulding Electrocardiograph 2100iq used an iOS device, and the predicate Spaulding IQ Electrocardiograph 1000 utilized a windows laptop to collect the data. The results of the testing showed that the devices produce comparable results.

Based on the above comparison data, it can be concluded that the Spaulding Electrocardiograph 2100iQ is as safe, effective, and performs as well as the predicate Spaulding iQ Electrocardiograph device. Testing has been completed regarding the differences between the two devices and the differences do not adversely affect safety and effectiveness.