May 30, 2018

SYNERGEN Technology Labs LLC
% Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct
Naples, Florida 34114

Re: K171019
Trade/Device Name: ScioCardio ECG Transmitter
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter And Receiver
Regulatory Class: Class II
Product Code: DRG
Dated: April 30, 2018
Received: April 30, 2018

Dear Daniel Kamm:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171019

Device Name
ScioCardio ECG Transmitter

Indications for Use *(Describe)*
ScioCardio ECG transmitter is a physiological ECG acquisition module. It records and transmits the data acquired, to a compatible mobile phone via Bluetooth low energy link, for visualization without making any analysis or filtering to the data acquired.

ScioCardio ECG transmitter acquires Lead II and Lead III ECG signals meeting the AAMI/ANSI/IEC standards for ambulatory ECG acquisition, via three electrodes attached to the patient's body.

ScioCardio ECG transmitter is a battery powered wearable device which allows the patient to be free to moving while wearing the device.

ScioCardio ECG transmitter transmits the acquired physiological signals in real-time to a compatible mobile phone where ScioCardio Mobile App is installed. ECG data is stored in the mobile phone verbatim without any sampling adjustment or any other modifications and also is displayed in the Mobile App.

ScioCardio ECG transmitter is a prescription only device which is intended for use under the supervision of a physician or those knowledgeable in all aspects of ECG morphology, rhythm and arrhythmia.

ScioCardio ECG transmitter and ScioCardio Mobile App are intended to be used on adult patients only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary, SYNERGEN TECHNOLOGY LABS LLC

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

Date Summary Prepared: January 26, 2017

Submitter's Identification:

SYNERGEN Technology Labs LLC
3131 McKinney Avenue, Suite 602
Dallas, Texas 75204

Summary Prepared by:
Sunil Konda, Vice President, Product
Direct: 214-643-6002
Mobile: 214-435-0633
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Device Name:
Trade /Proprietary Name: ScioCardio ECG Transmitter
Regulation Number: 870.2910
Regulation Name: Transmitters and receivers, physiological signal, radiofrequency
Regulatory Class: II
Product Code: DRG

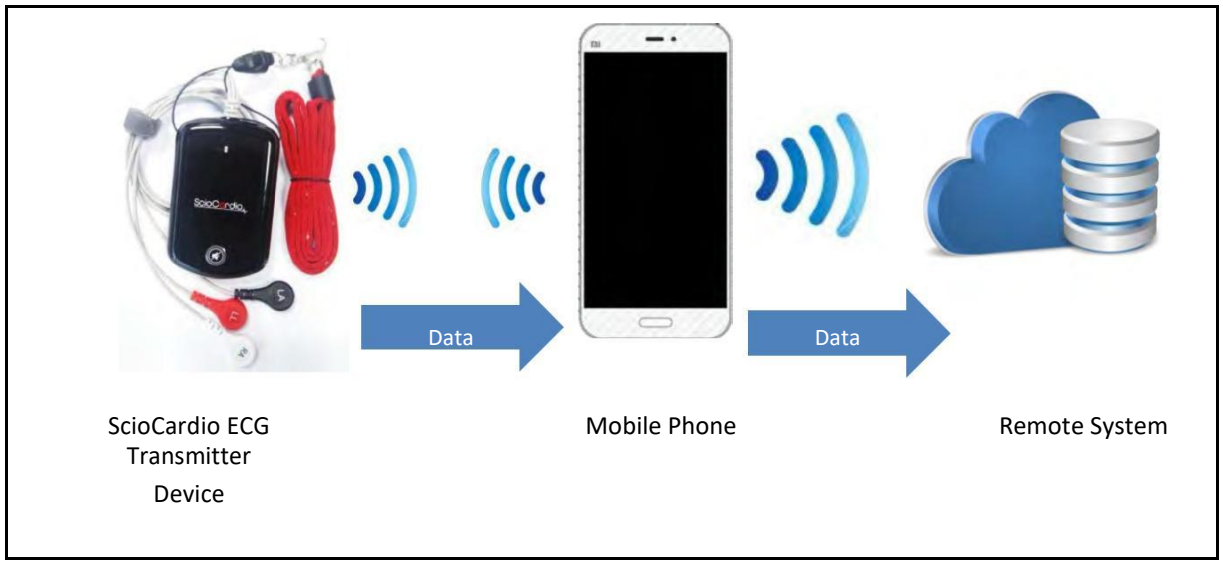
Legally Marketed Predicate Devices Information:

Trade/Device Name: Cardioline HD+ made by Cardioline S.p.A.
Premarket Notification K150289
Regulation Number: 870.2910
Regulation Name: Transmitters and Receivers, Physiological Signal, Radiofrequency
Regulatory Class: II
Product Code: DRG

Trade/Device Name: PocketECG v2 made by Medicalgorithmics LLC
Premarket Notification K112921
Regulation Number: 870.1025
Regulation Name: Arrhythmia Detector and Alarm
Regulatory Class: II
Product Code: DSI

Device Description:

ScioCardio ECG transmitter is a battery powered wearable device, capable of continuously capturing a body surface ECG from the patient, storing and transmitting the data to an external device or a system wirelessly. ECG signals are captured from the conventional solid gel electrodes worn on the body using a 3 lead ECG system. Raw ECG data is stored and transmitted wirelessly to any compatible device with Bluetooth Low Energy capability. This allows visualization, analysis and interpretation which can be used for a variety of applications such as ECG monitoring, heart rate monitoring, arrhythmia detection and analysis, out-patient monitoring etc. Other than the ECG data, ScioCardio ECG transmitter also captures, stores and transmits patient's motion data from an IMU sensor providing information about the patient's activities which can also be used in above mentioned analysis and interpretations. ScioCardio ECG transmitter is an always-on device. Data acquisition, storing and transmission are all done automatically and require no patient intervention other than initializing the device. ScioCardio ECG transmitter is small in form factor and has a higher battery life, making it possible for the user to wear the device comfortably for longer durations as per specific requirements.



Intended Use/Indications for use:

ScioCardio ECG transmitter is a physiological ECG acquisition module. It records and transmits the data acquired, to a
compatible mobile phone via Bluetooth low energy link, for visualization without making any analysis or filtering to the data acquired.

ScioCardio ECG transmitter acquires Lead II and Lead III ECG signals meeting the AAMI/ANSI/IEC standards for ambulatory ECG acquisition, via three electrodes attached to the patient's body.

ScioCardio ECG transmitter is a battery powered wearable device which allows the patient to be free to moving while wearing the device.

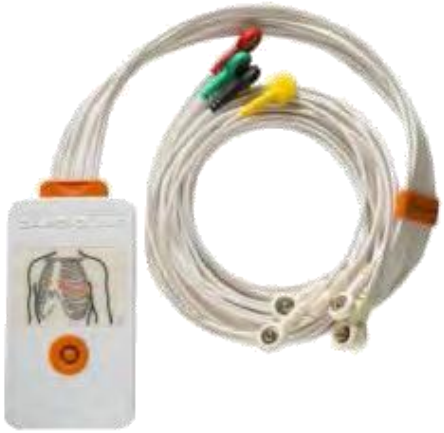
ScioCardio ECG transmitter transmits the acquired physiological signals in real-time to a compatible mobile phone where ScioCardio Mobile App is installed. ECG data is stored in the mobile phone verbatim without any sampling adjustment or any other modifications and also is displayed in the Mobile App.

ScioCardio ECG transmitter is a prescription only device which is intended for use under the supervision of a physician or those knowledgeable in all aspects of ECG morphology, rhythm and arrhythmia.

ScioCardio ECG transmitter and ScioCardio Mobile App are intended to be used on adult patients only.

Safety and Effectiveness: As shown in the table below, the design presents no issues regarding safety and effectiveness as compared to the predicate devices.

Table of comparison to Legally Marketed Devices:

Comparison Criteria	**K150289 Cardioline HD+ Product Code DRG**	**Synergen ScioCardio ECG Transmitter Product Code DRG**	**SE Discussion**
Photo			Equivalent technology employed: Battery operated Bluetooth ECG recorder/ transmitter
Basic Comparison	12 lead ECG without arrhythmia detection software, Bluetooth communication. Analysis program on the host is a separate product not marketed with the HD+.	3 Lead ECG without arrhythmia detection software. Uses Bluetooth communication. Compatible with 3rd party arrhythmia detection not marketed with the ScioCardio.	Like K150289, i.e. without arrhythmia but 3 leads instead of 12, same product code.
Mechanical Design	Portable plastic case with internal batteries.	SAME	Substantially equivalent.

Comparison Criteria	**K150289 Cardioline HD+ Product Code DRG**	**Synergen ScioCardio ECG Transmitter Product Code DRG**	**SE Discussion**
Indications for Use	HD+ is a physiological ECG acquisition module. HD+ transmits wireless, via Bluetooth to a PC or Tablet, the data acquired, without making any analysis or filtering on the data acquired. HD+ acquires 12-lead ECG waveforms meeting the standards for clinical and diagnostic applications (AAMI, ANSI, AHA, ACC) and offers full ECG acquisition. HD+ is designed to acquire and transmit a high quality ECG data allowing the patient to be free to moving (without cable connected to the processing unit). The HD+ transmits the acquired physiological signals in real-time to a computer/device where a compatible application is installed. All data acquired are sent via Bluetooth to a receiver that it can be a PC, tablet or device capable of receiving BT data. The ECG is transmitted verbatim to the receiving system, without LSB or sampling adjustment. It is up to the receiving system/application to perform the necessary processing such as (but not limited to) LSB scaling, signal filtering, Resting ECG analysis etc… The device HD+ is intended to be used on adult and on all pediatric patients. The device is intended for use by qualified, trained nurses and physicians operating in hospitals, clinics and medical practices.	ScioCardio ECG transmitter is a physiological ECG acquisition module. It records and transmits the data acquired, to a compatible mobile phone via Bluetooth low energy link, for visualization without making any analysis or filtering to the data acquired. ScioCardio ECG transmitter acquires Lead II and Lead III ECG signals meeting the AAMI/ANSI/IEC standards for ambulatory ECG acquisition, via three electrodes attached to the patient's body. ScioCardio ECG transmitter is a battery powered wearable device which allows the patient to be free to moving while wearing the device. ScioCardio ECG transmitter transmits the acquired physiological signals in real-time to a compatible mobile phone where ScioCardio Mobile App is installed. ECG data is stored in the mobile phone verbatim without any sampling adjustment or any other modifications and also is displayed in the Mobile App. ScioCardio ECG transmitter is a prescription only device which is intended for use under the supervision of a physician or those knowledgeable in all aspects of ECG morphology, rhythm and arrhythmia. ScioCardio ECG transmitter and ScioCardio Mobile App are intended to be used on adult patients only.	Like K112921 PocketECG v2 in that it records 3 leads (but we don't perform the analysis, that is done by a 3rd party program. Like K150289 Cardioline HD+ in that it the analysis is done by a 3rd party program, but we record 3 leads instead of 12. The compatible 3rd party analysis program (Telemed, K142349) works with either 12 or 3 leads. Substantially equivalent.

Comparison Criteria	**K150289 Cardioline HD+ Product Code DRG**	**Synergen ScioCardio ECG Transmitter Product Code DRG**	**SE Discussion**
ECG Leads	Up to 12 leads	3 leads	Substantially equivalent. Analysis programs can utilize either 3 or 12 lead ECG formats.
Communications	Bluetooth, Full ECG	Bluetooth Low Energy (BLE) Full ECG to Mobile Phone	SAME technology
Analysis	3rd party program	3rd party program	Includes aspects of both predicates
Power Source	2x AAA Batteries	Rechargeable 3.7V Li-ion battery	Battery operated: Substantially equivalent
Battery Life	10 Hours	120 Hours	The subject device has the longest battery life.
Powering the Device	Device is always on Powered on when the battery is inserted to the device, no power on/off button is provided	Device is always on Powered on when the battery is inserted to the device, no power on/off button is provided	SAME
Compatible Operating System	Windows 7 pro, Windows 8 pro, 32/64 bit	Android. (Future: iOS.)	Functionally equivalent, same purposes.
CMRR	115 dB	100 dB	
Sampling Rate	Up to 1000 s/s	Sampling rate 250Hz with 17 bit ADC resolution	Suitable for the intended use, substantially equivalent.
Bandwidth	0.05 - 300 Hz, according to sampling frequency	0.05-40 Hz (Required by ambulatory ECG requirements.)	Suitable for the intended use, substantially equivalent.
Input Range	+/ -400mV offset	10mV p-p over +/- 300mV DC offset	Specified slightly differently but equivalent and suitable for the intended uses.

Comparison Criteria	**K150289 Cardioline HD+ Product Code DRG**	**Synergen ScioCardio ECG Transmitter Product Code DRG**	**SE Discussion**
Standards Compliance	IEC 60601-1 medical electrical equipment - part 1: general requirements for basic safety and essential performance IEC 60601-2-25 Particular requirements for the basic safety and essential performance of electrocardiographs. IEC 60601-2-51 Medical electrical equipment. Particular requirements for safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs.	AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012, c1:2009/(r)2012 and a2:2010/(r)2012 (consolidated text) medical electrical equipment - part 1: general requirements for basic safety and essential performance IEC 60601-1-2 Edition 4.0 2014-02, medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic disturbances - requirements and tests. AAMI / ANSI / IEC 60601-2-47:2012, medical electrical equipment - part 2-47: particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems.	Equivalent standards used. EC57 (Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms) would apply to the 3rd party analysis program we do not supply. Re K150289, testing was done to multi-channel ECG standard. We tested to the more appropriate ambulatory standard.

The technological characteristics, including design, materials, composition, and energy source, are substantially the same, so there are no issues impacting safety and effectiveness.

Summary of non-clinical performance testing: Successful standards testing was performed in accordance with these International, FDA recognized Standards:
AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012, c1:2009/(r)2012 and a2:2010/(r)2012 (consolidated text) medical electrical equipment - part 1: general requirements for basic safety and essential performance

IEC 60601-1-2 Edition 4.0 2014-02, medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic disturbances - requirements and tests.

AAMI / ANSI / IEC 60601-2-47:2012, medical electrical equipment -- part 2-47: particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems.

Additional testing:
Battery life testing was performed to validate the claimed life of the rechargeable battery. The test results showed the battery lasted for longer than the specified time. (120 hours/5 days). Transmitter range testing was successfully conducted. Long term, short term, and patient simulator operability testing was successfully performed. Software and firmware validation and risk analysis using ISO 14971:2007, 2009 and 2012 was successfully performed according to predetermined test protocols.

Summary of clinical performance testing: Not required to establish substantial equivalence.

Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, Synergen Technology Labs concludes that the Synergen ScioCardio ECG Transmitter is substantially equivalent to the predicate device as described herein.