August 11, 2018

Bioserenity SAS
% Esin Yesilalan
Senior Regulatory Scientist
Voisin Consulting Inc. Life Sciences
222 Third Street, Suite 3121
Cambridge, Massachusetts 02142

Re: K173248
Trade/Device Name: Cardioskin
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter and Receiver
Regulatory Class: Class II
Product Code: DXH
Dated: July 23, 2018
Received: July 24, 2018

Dear Esin Yesilalan:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

Jessica E. Paulsen -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173248

Device Name
Cardioskin

Indications for Use *(Describe)*

Cardioskin is intended to aid the diagnostic evaluation for cardiac disorders by recording patient's ECG signals allowing to condition and monitor these signals. ECG data is stored, transferred and displayed for a review by a physician.
Cardioskin is designed to be used by a patient to transmit multiple-lead ECG signal to enable review at a physician's office, hospital or other remote locations under medical supervision.
Cardioskin target population is adults.

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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5. 510 (k) Summary

5.1 Submitter Information

Company Name:	BioSerenity SAS
Company Address:	47 boulevard de l'Hôpital 75013 Paris, France
Company Phone:	+33 157 274 456
Company Fax:	+33 186 953 093
Contact Person:	Mr. Quang Tran COO
Date the summary was prepared:	August 10, 2018

5.2 Device Identification

Trade Name:	Cardioskin
Common Name:	Cardioskin
Classification Name:	Telephone Electrocardiograph Transmitter and Receiver
Product Code:	DXH
Regulation Number:	21 CFR 870.2920
Device Class:	II

5.3 Identification of Predicate Devices

Device Name	SimplECG (Primary Predicate)	Master Caution Device (MCD™) (Secondary Predicate)
Manufacturer	Nanowear Inc.	Healthwatch Ltd.
510(k) Number	K161431	K142476
Regulatory Class	II	II
Clearance Date	November 30, 2016	February 17, 2015
Device Name	SimplECG (Primary Predicate)	Master Caution Device (MCD™) (Secondary Predicate)
Manufacturer	Nanowear Inc.	Healthwatch Ltd.
510(k) Number	K161431	K142476
Regulatory Class	II	II
Clearance Date	November 30, 2016	February 17, 2015

5.4 Device Description

Cardioskin is a wireless and wearable medical device.

It enables acquisition, recording, storage, transmission and display of 3-12 leads electrocardiogram (ECG) to analyze potential cardiac pathological abnormalities from adult patients in healthcare facility, at home or clinical research environment. It is intended to be used by trained patients and healthcare professionals only.

Cardioskin is composed of a garment, Cardioskin Textile, which is a T-Shirt where textile-based electrodes made of silver yarns are knitted and only functions on Cardioskin Battery and in association with a Cardioskin Recorder.

Cardioskin functioning is coupled with a smartphone/tablet compatible with an iOS or Android system, and a mobile application, the Cardioskin App.

A web-based information system, the Cardioskin Cloud, receives the ECG signals from the Cardioskin Recorder through a paired Wi-Fi connection for its long-term storage and display the signals in the web interface. The medical expert specialist, who prescribes the use of this device, should monitor its use and confirm the proper functioning of signal recording thanks to Cardioskin Cloud.

5.5 Indications for Use

Cardioskin is intended to aid in the diagnostic evaluation for cardiac disorders by recording patient's ECG signals allowing to condition and monitor these signals. ECG data is stored, transferred and displayed for a review by a physician.

Cardioskin is designed to be used by a patient to transmit multiple-lead ECG signal to enable review at a physician's office, hospital or other remote locations under medical supervision.

Cardioskin target population is adults.

5.6 Comparison to Predicate Devices

The Cardioskin device combines the functionality of the two predicate devices into a single device. Both predicate devices along with the subject device have the same intended use, and any differences in technological characteristics do not impact safety and effectiveness.

Table 5-1 provides the comparison to the predicate devices.

Table 5-1 Comparison to Predicate Devices

Feature	Cardioskin	SimplECG	Master Caution Device
Indication for Use Statement	Cardioskin is intended to aid the diagnostic evaluation for cardiac disorders by recording patient's ECG signals allowing to condition and monitor these signals. ECG data is stored, transferred and displayed for a review by a physician. Cardioskin is designed to be used by a patient to transmit multiple-lead ECG signal to enable review at a physician's office, hospital or other remote locations under medical supervision. Cardioskin target population is adults.	The SimplECG is intended to aid in the diagnostic evaluation of patients, 21 years of age and above, on the order of a physician, who experience transient symptoms which may suggest the need for monitoring to manually assess their cardiac rhythm disturbance. ECG data is recorded, stored, transferred and displayed wirelessly for review by a physician who is skilled in rhythm interpretation.	Master Caution Device (MCD) is intended to condition an electrocardiographic signal, so that it can be transmitted digitally via Bluetooth technology and cell-phone or communication device to a remote location. The Master Caution Device (MCD) is designed to be used by a patient to transmit a 12 lead ECG, posture and motion, respiration and skin temperature (IR) signals, in near real-time to enable review at a physician's office, hospital or other remote medical receiving center. Master Caution Device (MCD) target population is adults above the age of 21.
Intended use	Acquisition, record, storage, transmission and displaying of 3-12 lead ECGs	Capturing and displaying electrocardiogram signals	Acquisition, record, storage, transmission and displaying of 3-12 (3, 5, 12 leads) lead ECGs, posture and motion, respiration and skin temperature (IR) signals
Patient population	Adults above the age of 21		
User	Healthcare professional/technicians, patients		
Environment of Use	Healthcare facility (hospital, rehab centre) or at home		
Number of elements	CARDIOSKIN TEXTILE; CARDIOSKIN RECORDER;	The SimplECG Garment The SimplECG Communication Module	T-Shirt (h-Wear) and analysis and control processor (MasterCaution)
Report an event manually	Only for research	Patient logging of symptoms	Yes
ECG measures	Yes		
ECG electrodes	10 electrodes (+3 electrodes for research)	Nanosensor electrodes	10 electrodes
Acceleration sensor	Only for research	No	Yes

Respiration sensor	No	No	Yes
Skin temperature sensor	No	No	Yes
Sampling frequency	low resolution: ≈ 250 Hz standard: 1000Hz	250 Hz	1 000Hz
Power Supply	3.7V	1 AA Lithium battery (Energizer Ultimate Lithium AA)	3.7V
Physiological parameters transfer	Bluetooth		
Compatibility	Android, iOS	iOS	Android, iOS
Data depth	16 bits	24 bits	≥12 bits
Connectivity	2G/3G/4G/GPRS WiFi		
Data transmission	CARDIOSKIN APP; CARDIOSKIN CLOUD;	SimplECG Mobile Application Nanowear Web Application	Mobile health app: MasterCaution Mobile cloud solution: Master Caution Cloud
Standards	IEC 60601-1 Medical Electrical Equipment-Part 1: General Requirements for Safety. Collateral Standard: Safety Requirements for Medical Electrical Systems. IEC 60601-1-2 Medical Electrical Equipment Part 1-2: Collateral Standard: Electromagnetic Compatibility – Requirements and Tests. ISO 14971 Medical Devices- Application of risk management to medical devices		

5.7 Performance Data

Support for the substantial equivalence of Cardioskin was provided as a result of risk management and testing which included electrical and biological safety, performance and software tests. Testing has provided reasonable assurance of safety and effectiveness for the intended use and supports the substantial equivalence demonstration.

The cleaning and disinfection procedures must be applied depending on the components. Procedures are provided in the User Manual.

The textile materials used in Cardioskin are widely used in the textile industry.

Biocompatibility was assessed following ISO 10993 “Biological Evaluation of Medical Devices Part 1: Evaluation and Testing”. The skin contact of Cardioskin device is limited to 12 hours. Hence, per ISO 10993, Part 1, and the FDA-modified Matrix (“Use of International Standard ISO-10993 “Biological Evaluation of Medical Devices Part 1: Evaluation and

Testing") the following tests are conducted to determine biocompatibility of Cardioskin: Irritation and Sensitization.

The firmware in Cardioskin, the mobile app and the Cloud have been tested through verification and validation according to the IEC 62304:2006 standard and as per the FDA Guidance "General Principles for Software Validation". The results of the verification and validation activities demonstrate that the software meets the requirements for safety, function and intended use.

Electromagnetic compatibility and electrical safety testing of Cardioskin was conducted following recognized standards for electro-medical equipment. Compliance to the specific standard IEC 60601-2-47:2012 Part 2: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems regarding the operational and mechanical performance has been demonstrated.

5.8 Conclusion

Cardioskin is similar in intended use to the predicate. The technological differences were evaluated by non-clinical and limited clinical testing which support the safety and effectiveness of Cardioskin for its intended purposes. Therefore, Cardioskin is substantially equivalent to its legally marketed predicate.