DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 30, 2016

Nanowear Inc.
% Melissa Walker
President and CTO
Graematter, Inc.
1324 Clarkson Clayton Center
St Louis, Missouri 63011

Re: K161431
Trade/Device Name: SimplECG
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter and Receiver
Regulatory Class: Class II
Product Code: DXH
Dated: October 21, 2016
Received: October 25, 2016

Dear Melissa Walker:

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.

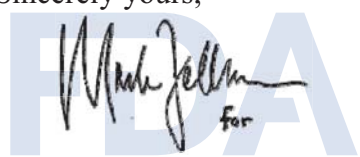
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



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)*
K161431

Device Name
SimplECG

Indications for Use *(Describe)*
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.

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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K161431 510(k) Summary

SimplECG Summary

Submitter's information

Nanowear Inc
53 Boerum Place, Suite 3F
Brooklyn, NY 11201
United States
Phone: (718) 637-4815

Contact: Venk Varadan
53 Boerum Place, Suite 3F
Brooklyn, NY 11201
United States
(718) 637-4815
Date: October 20, 2016

Device/ classification name

The device trade name(s) and classification name(s) for the New Device are:

- Trade Name: SimplECG
- Regulation Name: Telephone Electrocardiograph Transmitter and Receiver
- Classification Name: 21CFR §870.2920
- Class II
- Product Code DXH

Predicate device(s)

The predicate devices are:

- K143032 eMotion Faros ECG Mobile cleared on March 29, 2015 from Mega Electronics Ltd.
- K142476 Master Caution Device cleared on February 17, 2015 from Healthwatch, Ltd.

Based on a review of the FDA's Recalls database, the predicate devices have not been the subject of a design-related recall.

No reference devices were used in this submission.

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SimplECG Summary, Continued

Device description

The Nanowear SimplECG ("SimplECG") device is a wearable garment (either a shirt or brassiere) that is magnetically attached to a communication module which is secured in place by an elastic pouch. The SimplECG is designed for reliability, patient comfort and ease of use in clinical-quality electrocardiogram ("ECG") applications. The SimplECG device does not perform any automatic beat or rhythm classification on the acquired ECG data. The intended duration of use of the SimplECG device is up to 24 hours.

The SimplECG Communication Module can collect continuous ECG data from the garment, securely stores it and transfers to a compatible mobile device (iOS), which then uploads the recorded ECG data to a secure Nanowear Inc. ("Nanowear") server for review by a medical professional (inclusive of a physician, nurse or technician). The device consists of four (4) components:

- The SimplECG Garment: a shirt or brassiere, consisting of a network of nanosensors integrated directly into the garment, that collects ECG signals directly from the skin which are then captured by the communication module.
- The SimplECG Communication Module*: collects, stores and wirelessly transmits ECG signals from the garment to the patient mobile device.
- The SimplECG Mobile Application: allows for patient logging of symptoms and transmission of ECG recordings to a secure, remote server through a patient-supplied mobile device operating on Apple iOS.
- The Nanowear Web Application: allows initiation of a test, and storage and review of patient ECG data sent from the Mobile Application to the server.

*The electronic enclosure for the SimplECG Communication Module is made of Nylon/PA2200.

Indications for use

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.

The Indications for Use statement for the predicate devices are not identical. However, the differences do not alter the intended use of the device, nor do they affect the safety and effectiveness of the SimplECG relative to the predicate. Both the SimplECG device and the predicate devices have the same intended use for capturing and displaying electrocardiogram signals.

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SimplECG Summary, Continued

Technology comparison

The table below shows a comparison of technical characteristics between the SimplECG (new device) and the predicate devices.

Characteristic	SimplECG New Device	eMotion Faros ECG Mobile Predicate Device	MasterCaution Device Predicate Device
Bluetooth	Yes	Yes	Yes
Remote transmission	Yes	Yes	Yes
Shaving / skin prep	No	Yes	N/A
Electrode type	Nanosensor	Standard electrode	N/A
Works in presence of moisture / perspiration	Yes	No	No
Patient symptom logging on smartphone	Yes	No	No
ECG analysis	No	No	No
Collects other health parameters	No	Yes	Yes
Web interface	Yes	Yes	Yes
Frequency response	0.05 Hz to 65 Hz	NA	0.05 – 120 Hz
ECG channels	3 channel (male)/ 1 channel (female)	Online: 1-channel Offline: 3-channels	NA
Resolution	24 bit	24 bit	12 bit
Sample rate	250 Samples/second	Selectable: 100, 125, 250, 500, 1000 Hz	1 kHz
Memory	microSD card	Internal	NA
Memory type/capacity	2 GB	1GB or more	NA
Power Supply- Battery type	1 AA Lithium battery (Energizer Ultimate Lithium AA)	3.7 V Li-ion battery	Type unknown 3.7 V @ 2450 mAh
Data Transfer	Bluetooth, Cellular network / Wi-Fi	Bluetooth, Cellular network / Wi-Fi	Bluetooth, Cellular network / Wi-Fi
Software Interface	iOS-based (9 or later), web-based software	Web-based software	Android 4.2 / iOS 6+, web-based software
Communication Module Dimensions	3.32” x 2.99” x 0.82”	1.89” x 1.14” x 0.47”	2.95” x 2.48” x 0.7”
Communication Module Weight	3.43 ounces	0.45 ounces	3.17 ounces
Electrodes	Integrated in device	NA	Integrated in device
Usage Environment	Healthcare facility or Home environment	Healthcare facility or Home environment	Healthcare facility or Home environment
Environmental Operating Temp	5^0C to 45^0C	Unknown	Unknown
Storage Temp	-25^0C to 60^0C	Unknown	Unknown

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SimplECG Summary, Continued

Performance testing

Conformance for the SimplECG device is claimed to the standards listed in the table below.

Standard Number	Title
AAMI / ANSI 60601-1:2005 /(R) 2012	Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
AAMI / ANSI 60601-1-2:2014	Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests
IEC 60601-2-47:2012	Medical Electrical Equipment – Part 2-47: Particular requirements for Basic Safety and Essential Performance of Ambulatory Electrocardiographic Systems
ISO 10993:2009	Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process; Part 5: Tests for Cytotoxicity; Part 10: Tests for Irritation and Skin Sensitization
ASTM D4169-09	Standard Practice for Performing Testing of Shipping Containers and Systems Distribution Cycle II
ISO 14971:2007	Medical devices — Application of risk management to medical devices

Pre-clinical performance data to support substantial equivalence

In addition to testing required to support conformance to the above listed standards, pre-clinical testing included the following:

- Usability Assessment
- Performance Testing – Bench
  - Equivalency Testing of SimplECG to Standard of Care Device
  - Performance Testing of SimplECG under typical use conditions
- Performance Testing - Communication Module
- Performance Testing - Nanosensor Garment
- Performance Testing - Firmware

Clinical performance data

Clinical data was not required for this submission

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SimplECG Summary, Continued

Summary - substantial equivalence to predicate.

Results of the Performance testing for Communication Module, Nanosensor garment and the Firmware show that -

- SimplECG device uses the same standard wireless transmission protocols as the predicate devices.
- The ECG acquisition performance of the SimplECG is comparable to the predicate devices and does not raise any new concerns over safety or effectiveness.

Results of the Usability Assessment presented show that -

- SimplECG device's user interfaces were evaluated to ensure that any minor differences from the predicates do not raise any safety or effectiveness concerns.

Results of the Performance Testing - Bench presented show that

- The differences in the technological characteristics do not raise any new issues affecting the safety and effectiveness of the SimplECG device as compared to the predicate devices.

Conclusions

Based on the comparability of the intended use, the technological characteristics, and the performance data, the SimplECG device is substantially equivalent to the predicate devices.