November 6, 2020

Nanowear Inc.
% Melissa Walker
President & CTO
Graematter, Inc.
1324 Clarkson Clayton Ctr, #332
St Louis, Missouri 63011

Re: K201669
Trade/Device Name: SimpleSENSE
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter And Receiver
Regulatory Class: Class II
Product Code: DXH, DSB, BZQ, DPS, DQD
Dated: October 4, 2020
Received: October 6, 2020

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. 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer Shih
Assistant Director
Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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)*
K201669

Device Name
SimpleSENSE

Indications for Use *(Describe)*
The SimpleSENSE System is intended for use at home, or at a healthcare facility, under the direction of a licensed medical professional, to record, display and store the following physiological data: a) 2 leads of Electrocardiogram; b) Respiration rate measured through thoracic impedance; c) Heart Sounds; and d) Activity including posture. The device is intended for use when the clinician decides to evaluate the physiologic signals of adult patients as an aid to diagnosis and treatment. The SimpleSENSE System is intended to be used by patients at rest and not performing any activities or movements. ECG recordings are indicated for the manual assessment of cardiac rhythm disturbances. The device does not produce alarms and is not intended for active patient monitoring (real-time). The device is not intended for use as life supporting equipment on high-risk patients such as critical care patients. The device is not intended for use in the presence of a pacemaker.

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.

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K201669 510(k) Summary

Submitter's information

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United States
718-637-4815

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Phone: 718-637-4815
Date: June 15 2020

Classification

The classification for the new device is shown in the table below.

21 CFR Reference	Product Code	Class	Trade Name	Classification Name
§870.2920	DXH	2	SimpleSENSE	Transmitters and Receivers, Electrocardiograph, Telephone
§870.2770	DSB	2		Plethysmograph, Impedance
§868.2375	BZQ	2		Monitor, Breathing Frequency
§870.2340	DPS	2		Electrocardiograph
§870.1875	DQD	2		Stethoscope, Electronic

Predicate devices

The predicate device is:

- K161431 SimplECG cleared on 11/30/2016 from Nanowear, Inc.

The following devices are considered as reference devices:

- K160981 Patient Monitor, models elite V5, elite V6 and elite V8 cleared on 12/22/2016 from Edan Instruments, Inc.
- K151319 Eko Electronic Stethoscope System cleared on 5/18/2015 from Eko Devices, Inc.

Indications for use

The SimpleSENSE System is intended for use at home, or at a healthcare facility, under the direction of a licensed medical professional, to record, display and store the following physiological data: a) 2 leads of Electrocardiogram; b) Respiration rate measured through thoracic impedance; c) Heart Sounds; and d) Activity including posture. The device is intended for use when the clinician decides to evaluate the physiologic signals of adult patients as an aid to diagnosis and treatment. The SimpleSENSE System is intended to be used by patients at rest and not performing any activities or movements. ECG recordings are indicated for the manual assessment of cardiac rhythm disturbances. The device does not produce alarms and is not intended for active patient monitoring (real-time). The device is not intended for use as life supporting equipment on high-risk patients such as critical care patients. The device is not intended for use in the presence of a pacemaker.

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Device Comparison, Continued

Device description	The Nanowear SimpleSENSE device is the next generation diagnostic monitoring technology that captures electrocardiographic (ECG) signals, respiration rate though thoracic impedance, heart sounds, activity including posture with sensors embedded on a wearable textile garment. The signals are stored and wirelessly transmitted to a smartphone, and forwarded to a medical professional for review. The garment is designed to be unobtrusive to everyday activity and provide an easy and efficient means of capturing ECG, respiration rate, heart sounds and activity data from patients. The garment is designed to be unobtrusive to everyday activity and provide an easy and efficient means of capturing ECG data from patients. The device consists of three (3) components: • The SimpleSENSE Garment: an integrated network of nanosensor electrodes for measuring ECG and respiratory rate from thoracic impedance, and incorporating a MEMS microphone for measuring heart sounds. • The SimpleSENSE Signal Acquisition Unit (SAU): data acquisition, storage, and transmission to an iPhone 7 using iOS 13.4. Incorporates an accelerometer to measure activity. • The SimpleSENSE Mobile Application: mobile application for to start/stop a recording and to forward the test report to the medical professional.

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Device Comparison, Continued

Characteristics The table below provides a comparison of the New Device with the predicate and reference devices.

Characteristic	Nanowear Inc. SimpleSENSE - New Device Current Submission	Nanowear Inc. SimplECG K161431	Edan Instruments, Patient Monitor, models elite V5, elite V6 and elite V8 K160981	Eko Devices Inc. Eko Electronic Stethoscope System K151319	Comparison
Indications for Use Statement	The SimpleSENSE system is intended for use at home, or healthcare facility, under the direction of a licensed medical professional, to record, display and store the following physiological data: a) 2 leads of Electrocardiogram b) Respiration rate measured through thoracic impedance; c) Heart Sounds; and d) Activity including posture. The device is intended for use when the clinician decides to evaluate the physiologic signals of adult patients as an aid to diagnosis and treatment. The SimpleSENSE System is intended to be used by patients at rest and not performing any activities or movements. ECG	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 monitors are intended to be used for monitoring, storing, and reviewing of, and to generate alarms for, multiple physiological parameters of adults, pediatrics and neonates. The monitors are intended for use by trained healthcare professionals in hospital environments. The monitored physiological parameters include: ECG, respiration (RESP), temperature (TEMP), oxygen saturation of arterial blood (SpO2), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), carbon dioxide (CO2), cardiac output (C.O.), anesthetic gas (AG), bispectral index (BIS), respiration mechanics (RM)	The Eko Electronic Stethoscope System is intended to be used as a part of a physical assessment of a patient by healthcare professionals for diagnostic decision support in clinical settings. Eko is intended for use on pediatric and adult patients. It can electronically amplify, filter and transfer sounds to the accompanying mobile application for storage and sharing. It can used to record heart sounds and cardiac murmurs, bruits, respiratory sounds and abdominal sounds during physical	The SimpleSENSE offers the same ECG measures as the SimplECG; heart sounds as in the Eko device, and a subset of the measures included in the Edan Patient Monitor device. The absence of the measures does not affect the substantial equivalence of the New Device.

Characteristic	Nanowear Inc. SimpleSENSE - New Device Current Submission	Nanowear Inc. SimplECG K161431	Edan Instruments, Patient Monitor, models elite V5, elite V6 and elite V8 K160981	Eko Devices Inc. Eko Electronic Stethoscope System K151319	Comparison
	recordings are indicated for the manual assessment of cardiac rhythm disturbances. The device does not produce alarms and is not intended for active patient monitoring(real-time). The device is not intended for use as life supporting equipment on high-risk patients such as critical care patients. The device is not intended for use in the presence of a pacemaker.		and impedance cardiography (ICG). BIS is intended for use on adult and pediatric patients. ICG monitoring is intended for use on adults only. The arrhythmia detection and ST Segment analysis are intended for adult patients. The monitors are additionally intended for use during patient transport inside hospitals. The monitors are not intended for MRI environments.	examination in normal patients or those with suspected diseases of the cardiac, vascular, pulmonary or abdominal organ systems.	
Product Code(s)	DXH, DPS, DQD, DSB, BZQ	DXH	MHX, DSI, DRT, CBQ, DXN, DSK, CBR, DQA, NHO, CBS, NHQ, NHP, CCK, DSB, CCL, BZQ, BZK, DPS, FLL, DRG, MLD	DQD	Similar

Characteristic	Nanowear Inc. SimpleSENSE - New Device Current Submission	Nanowear Inc. SimplECG K161431	Edan Instruments, Patient Monitor, models elite V5, elite V6 and elite V8 K160981	Eko Devices Inc. Eko Electronic Stethoscope System K151319	Comparison
Acquired Data	Electrocardiogram (EKG/ECG) Respiration Rate derived from thoracic impedance Heart Sounds	Electrocardiogram (EKG/ECG)	ECG, Respiration Rate, Temperature SpO2, pulse rate non-invasive blood pressure (NIBP), invasive blood pressure (IBP), carbon dioxide (CO2), cardiac output (C.O.), anesthetic gas (AG), Bispectral Index (BIS), respiration mechanics (RM) Impedance Cardiography (ICG).	Heart Sounds	Same measures as those found in the predicate & reference devices. The New Device captures the ECG signal in the same way as the SimplECG predicate. The New Device captures some of the measures in the Edan reference and the heart sounds as in the Eko reference. The absence of some measures does not affect the substantial equivalence of the SimpleSENSE device.
Sensor Technology	Electrocardiogram (EKG/ECG): Textile-based Nanosensors	Electrocardiogram (EKG/ECG): Textile-based Nanosensors	Not Applicable	Not Applicable	Same sensors as in the SimplECG device are used to capture signals
	Respiration Rate: Textile-based Nanosensors measure thoracic impedance and respiration is derived from thoracic impedance	Not Applicable	Thoracic Impedance/Impedance Cardiogram (ICG), ECG: Disposable Silver or Silver/Silver Chloride electrode. Respiration Rate: derived from thoracic impedance	Not Applicable	Both the New Device and the Edan reference measure and derive respiration rate using thoracic impedance captured via a sensor. The sensors in the two devices are different, however both types of sensors are used for

Characteristic	Nanowear Inc. SimpleSENSE - New Device Current Submission	Nanowear Inc. SimplECG K161431	Edan Instruments, Patient Monitor, models elite V5, elite V6 and elite V8 K160981	Eko Devices Inc. Eko Electronic Stethoscope System K151319	Comparison
					physiologic signal capture in other cleared devices.
	Heart Sound: Microelectromechanical (MEMS) microphone	Not Applicable	Not Applicable	Heart Sound: Uses a standard stethoscope diaphragm. Method of transduction and digitization of sound waves is not Available	The SimpleSENSE device uses a different sensor than the Eko reference. However, the signal acquisition and location used in both the SimpleSENSE device and the Eko reference are similar.
Signal acquisition method	Electrocardiogram (EKG/ECG): Standard Bipolar lead instrumentation amplifier and Sigma-Delta Analog to Digital Converter.	Electrocardiogram (EKG/ECG): Standard Bipolar lead instrumentation amplifier and Sigma-Delta Analog to Digital Converter	Not Applicable	Not Applicable	The signal acquisition method in the New Device for capturing ECG signal is the same as the SimplECG predicate.
	Respiration rate: Thoracic Impedance is measured using four-point probe using low amplitude current applied to the body and impedance measured from voltage drop derived from thoracic impedance. (Respiration Rate detection range 6 – 22	Not Applicable	Thoracic Impedance/Impedance Cardiograph: four-point probe using low amplitude current applied to the body and impedance measured from voltage drop. Respiration Rate: derived from thoracic impedance	Not Applicable	The signal acquisition method for capturing thoracic impedance is the same as the Edan reference.

Characteristic	Nanowear Inc. SimpleSENSE - New Device Current Submission	Nanowear Inc. SimplECG K161431	Edan Instruments, Patient Monitor, models elite V5, elite V6 and elite V8 K160981	Eko Devices Inc. Eko Electronic Stethoscope System K151319	Comparison
	breaths per minute (BPM) with accuracy ± 2 BPM)				
	Heart Sound: solid state Microelectromechanical (MEMS) microphone embedded in garment and located near Apex of heart.	Not Applicable	Not Applicable	Heart Sound: sensor embedded in a standard stethoscope attachment that can amplify, digitize and transmit data.	The signal acquisition method for detecting heart sounds is similar to the Eko reference. Both devices are placed in similar locations to detect and capture heart sounds.
Display Type	No on-device display.	No on-device display.	On Device Display of waveforms acquired and derived parameters is available. Data can be downloaded from the device through an Ethernet connection or a USB connection.	No on-device display. Display of data is available on a smartphone through a smartphone app or on the web using web services.	Data display for the New Device is the same as the SimplECG predicate and the Eko reference that rely on wireless transmission and display on a smartphone or web-based display.
Display Requirement	User provided display hardware for a healthcare professional to view the recorded data. A general-purpose PC/Laptop/Desktop or mobile device may be used.	User provided display hardware for a healthcare professional to view the recorded data. A general-purpose PC/Laptop/Desktop may be used.	No requirement for additional user provided hardware for display	Display available through User provided smartphone or tablet. Display also available through Web browser on any Laptop/PC/Desktop.	The Edan reference includes a display (hardware) while the New Device, the SimplECG, and the Eko reference all display the data on the user's hardware and via web based display.
Power Source	Internally powered using Li-Ion rechargeable battery	Single Use Lithium AA type batteries	Rechargeable Lithium-Ion Battery and AC Mains supported.	Internally powered using Li-Ion rechargeable battery	All of the devices are able to operate on battery power. The Edan reference has an option

Characteristic	Nanowear Inc. SimpleSENSE - New Device Current Submission	Nanowear Inc. SimplECG K161431	Edan Instruments, Patient Monitor, models elite V5, elite V6 and elite V8 K160981	Eko Devices Inc. Eko Electronic Stethoscope System K151319	Comparison
					for use with an AC Main.
Internal Memory/data	Removeable MicroSD card	Removeable MicroSD card	Solid state memory non-removeable.	Solid state memory non-removeable	All devices use memory devices to store the data collected. The New Device and the SimplECG predicate use removeable cards while the Edan and Eko references use non-removable memory devices.
Communication Interface	Wireless transceiver using Bluetooth	Wireless transceiver using Bluetooth	USB connection or Ethernet connection	Wireless transceiver using Bluetooth	The New Device uses the same communication interface as the SimplECG predicate and Eko reference. The Edan reference uses a non-wireless interface.
Access to recorded data	Data is transferred to the iPhone, which is then shared with the healthcare professional. For redundancy, encrypted data is also stored in the removeable storage medium.	Data is transferred to the iPhone, which is then shared with the healthcare professional. For redundancy, encrypted data is also stored in the removeable storage medium. Data is transferred from the device to a web server and a Web interface is used to access the data.	Trends data can be downloaded using proprietary clinical management software.	Data is transferred and stored in .wav format and can be retrieved from a web interface	Access to the data output for the New Device is the same as the SimplECG and similar to the Eko reference. The Edan reference uses proprietary software to manage their downloadable data.

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Device Comparison, Continued

Discussion - similarities

The similarities of the New Device to one or more of the predicate/references are:

- Sensor technology is the same as the SimplECG predicate device sensor
- Same measures as those found in the predicate and reference devices.
- Same sensors as in the SimplECG device are used to capture signals (except heart sounds)
- Both the New Device and the Edan reference measure and derive respiration rate using thoracic impedance captured via a sensor.
- The signal acquisition method for capturing ECG signal is the same as the SimplECG predicate.
- The signal acquisition method for capturing thoracic impedance is the same as the SimplECG predicate.
- The signal acquisition method for detecting heart sounds is similar to the Eko reference. Both devices are placed in similar locations to detect and capture heart sounds.
- Data display for the New Device is the same as the SimplECG predicate and Eko reference that rely on wireless transmission and display on a smartphone or web-based display.
- The Edan reference includes a display (hardware) while the New Device, the SimplECG predicate, and the Eko reference displays the data on the user's hardware or via web based display.
- All of the devices are able to operate on battery power. The Edan reference has an additional option for use with an AC Main.
- All of the devices listed use memory devices to store the data collected. The New Device and the SimplECG predicate use removeable cards while the Edan and Eko reference devices use non-removable memory devices.
- The New Device uses the same communication interface as the SimplECG predicate and Eko reference device.
- Access to the data output for the New Device is the same as the SimplECG and similar to the Eko reference.

Discussion - differences

The differences between the New Device and the predicate/reference devices are:

- The New Device does not capture all of the measures in the Edan reference.
- The sensors in the new device and Edan reference are different, however both types of sensors are used for physiologic signal capture in other cleared devices.
- The SimpleSENSE device uses a different sensor than the Eko reference. However, the signal acquisition and location used in both the SimpleSENSE device and the Eko reference are similar types of sensors.
- The Edan reference uses a wired interface.
- The Edan reference uses proprietary software to manage their downloadable data.

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Device Comparison, Continued

Performance testing	Performance testing for the SimpleSENSE device included the following: • Verification of multiparametric data capture • Verification of Bluetooth and iPhone connectivity • Verification of encryption of acquired data • Battery safety and charging status indication • SAU performance and durability • Durability, capacity, and data storage testing of the microSD card • Battery charger verification • Biocompatibility of the garment • Electrocardiograph sensor performance • Electrical current requirements for transthoracic impedance sensor • MEMS microphone testing • Garment conductive inlays testing for flexibility and electrical performance • Garment compression requirements • Garment fastening mechanisms • Use cycles for the base garment • Shelf life • Equivalency testing against predicate/reference devices Performance testing demonstrated performance to design specifications.
Conclusion	The performance data provided demonstrate that the SimpleSENSE device is substantially equivalent to the indicated predicate device.