September 22, 2021

Nanowear Inc.
Venkatesh Varadan
CEO
53 Boerum Place, Suite 3F
Brooklyn, New York 11201

Re: K212160
Trade/Device Name: SimpleSENSE Platform
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter and Receiver
Regulatory Class: Class II
Product Code: DXH, DQD, DSB, BZQ, DPS
Dated: August 19, 2021
Received: August 23, 2021

Dear Venkatesh Varadan:

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,

for

Jennifer Shih Kozen
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212160

Device Name
SimpleSENSE Platform

Indications for Use *(Describe)*
The SimpleSENSE Platform 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; d) Activity including posture; and e) other validated data sources. The SimpleSENSE Platform is intended for use when the licensed medical professional decides to evaluate the physiologic signals of adult patients as an aid to diagnosis and treatment. The SimpleSENSE Platform 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 SimpleSENSE Platform does not produce alarms and is not intended for active patient monitoring (real-time). The SimpleSENSE Platform is not intended for use as life supporting equipment on high-risk patients such as critical care patients. The SimpleSENSE Platform 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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510(K) SUMMARY
PER 21 CFR §807.92

1. SUBMITTER'S INFORMATION

Nanowear Inc.

Contact: Venkatesh Varadan

53 Boerum Pl, Suite 3F

Brooklyn, NY 11201

United States

Phone: 718-637-4815

Date: June 30, 2021

2. 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 Platform	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

3. PREDICATE DEVICE

The predicate device is:

- K201669 SimpleSENSE cleared on November 6, 2020, from Nanowear Inc.

4. INDICATIONS FOR USE

The SimpleSENSE Platform 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; d) Activity including posture; and e) other validated data sources. The SimpleSENSE Platform is intended for use when the licensed medical professional decides to evaluate the physiologic signals of adult patients as an aid to diagnosis and treatment. The SimpleSENSE Platform 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 SimpleSENSE Platform does not produce alarms and is not intended for active patient monitoring (real-time). The SimpleSENSE Platform is not intended for use as life supporting equipment on high-risk

patients such as critical care patients. The SimpleSENSE Platform is not intended for use in the presence of a pacemaker.

5. DEVICE DESCRIPTION

The Nanowear SimpleSENSE Platform is the next generation diagnostic monitoring technology that captures electrocardiographic (ECG) signals, respiration rate though thoracic impedance, heart sounds, activity including posture and movement with sensors embedded on a wearable textile garment. The signals are stored and wirelessly transmitted to a smartphone, which is then forwarded to a medical professional for review.

The garment is designed to be unobtrusive to everyday activity and provide an easier and more efficient means of capturing ECG data from patients. The device consists of a combination of:

- The SimpleSENSE Garment: an integrated network of nanosensor electrodes for measuring ECG and respiratory rate from thoracic impedance. A MEMS microphone for measuring heart sounds.
- The SimpleSENSE Signal Acquisition Unit (SAU): data acquisition, storage, and transmission to a phone running iOS or Android. An accelerometer to measure activity.
- The SimpleSENSE Mobile Application: mobile application to start/stop a recording, logging symptoms, and data transmission.
- SimpleSENSE Web Server: allows initiation of a test, storage, and review of prescribed test data by a medical professional.

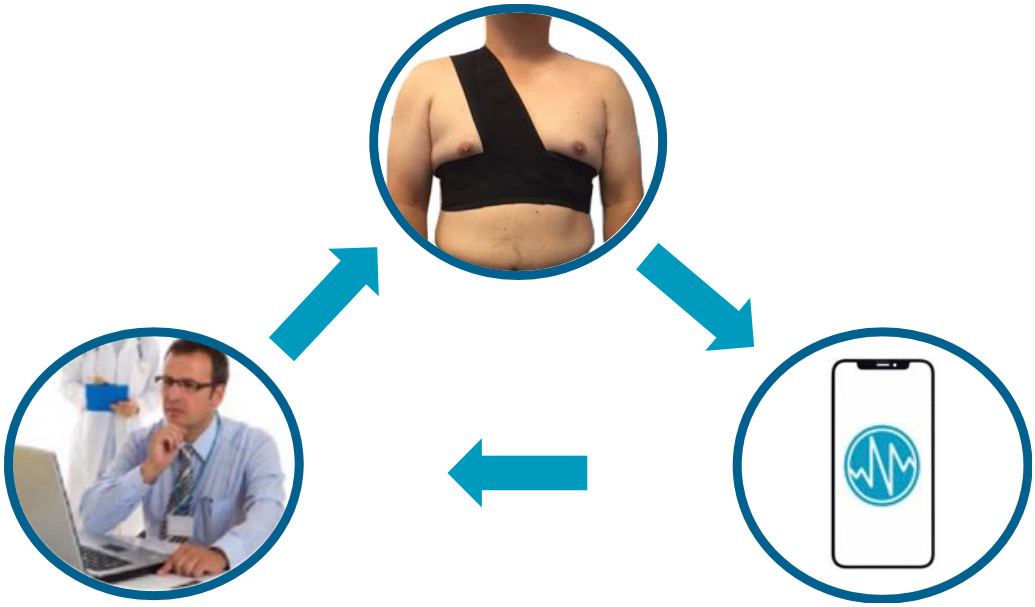

FIGURE 1: SIMPLESENSE PLATFORM CLINICAL MODEL OF DATA COLLECTION, TRANSMISSION AND REVIEW

6. INTENDED USE

The Nanowear SimpleSENSE Platform is intended for use by licensed medical professionals or patients to record, store, and transfer electrocardiogram (ECG), respiratory rate, heart sounds, and activity including posture and movement.

7. CHARACTERISTICS

The table below delineates the similarities and differences between the cleared SimpleSENSE System, and the proposed SimpleSENSE Platform. The table includes comparisons of the system features of the devices. Any differences between the two designs have been marked with **bold** font which are further discussed below the table.

TABLE 1: PREDICATE COMPARISON: SYSTEM DESIGN

	Nanowear Inc. SimpleSENSE System	**Nanowear Inc. SimpleSENSE Platform**
510(k) Number	K201669	To be assigned
Indication Statement	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.	The SimpleSENSE **Platform** 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; d) Activity including posture; and **e) other validated data sources**. The **SimpleSENSE Platform** is intended for use when the **licensed medical professional** decides to evaluate the physiologic signals of adult patients as an aid to diagnosis and treatment. The SimpleSENSE **Platform** 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 **SimpleSENSE Platform** does not produce alarms and is not intended for active patient monitoring (real-time). The **SimpleSENSE Platform** is not intended for use as life supporting equipment on high-risk patients such as critical care patients. The **SimpleSENSE Platform** is not intended for use in the presence of a pacemaker.
Product Code	DXH, DSB, BZQ, DPS, DQD	Same
Acquired Data	• Electrocardiogram (EKG/ECG) • Respiration Rate derived from thoracic impedance • Heart Sounds	Same

Sensor Technology	• Electrocardiogram (EKG/ECG): Textile-based Nanosensors • Respiration Rate: Textile-based Nanosensors measure thoracic impedance and respiration is derived from thoracic impedance • Heart Sound: Microelectromechanical (MEMs) microphone	Same
Signal acquisition method	• Electrocardiogram (EKG/ECG): Standard Bipolar lead instrumentation amplifier and Sigma-Delta Analog to Digital Converter. • 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. • Heart Sound: solid state Microelectromechanical (MEMs) microphone embedded in garment and located near Apex of heart.	Same
Display Type	No on-device display.	Same
Display Requirement	User provided display hardware for a healthcare professional to view the recorded data. A general-purpose PC/Laptop/Desktop may be used.	Same
Power Source	Internally powered using Li-Ion rechargeable battery	Same
Internal Memory/data	Removeable MicroSD card	Same
Communication Interface	Wireless transceiver using Bluetooth	Same
Access to recorded data	Data is transferred to the **iPhone**, which is then shared with the healthcare professional via **email**. For redundancy, encrypted data is also stored in the removeable storage medium.	Data is transferred to the **smart phone**, which is then shared with the healthcare professional via **the SimpleSENSE Web Server**. For redundancy, encrypted data is also stored in the removeable storage medium.

8. DISCUSSION OF KEY SYSTEM DIFFERENCES

8.1. Indications for Use

The primary change to the Indications for Use is the ability for SimpleSENSE Platform to record, display and store additional data sources. New data sources are validated for

compatibility with the SimpleSENSE Web Server to ensure proper display and synchronicity of the new data with existing data.

8.2. Access to Recorded Data

The Android OS App is included in the SimpleSENSE Platform to accommodate users that do not have access to an Apple iPhone running iOS. The Android OS App is essentially identical to the iOS App, with minor differences to accommodate user interface differences associated with Android OS compared to iOS.

The SimpleSENSE Web Server automates report/data delivery from patient to physician and provides the physician a single location (web application) to service their patient's data. The SimpleSENSE Web Server is a means of accessing patient data instead of requiring patient user intervention to email a report to their physician.

9. COMPARISON OF TECHNICAL CHARACTERISTICS

The table below delineates the differences between the cleared SimpleSENSE System, and the proposed SimpleSENSE Platform. The table includes comparisons of technical characteristics. Any differences between the two designs have been marked with **bold** font which are further discussed below the table.

TABLE 2: PREDICATE COMPARISON: TECHNICAL CHARACTERISTICS

Characteristic	Category	New Device SimpleSENSE Platform	Predicate SimpleSENSE System
Frequency response	ECG	0.05 Hz - 65 Hz	Same
	Thoracic Impedance	0.05 Hz - 65 Hz	Same
	Heart Sound	0.05 Hz - 236 Hz	Same
	Accelerometer	0-25 Hz	Same
Channels	ECG	2 channels	Same
	Thoracic Impedance	2 channels	Same
	Heart Sound	1 channel	Same
	Accelerometer	1 channel	Same
Resolution	ECG	24-bit	Same
	Thoracic Impedance	24-bit	Same
	Heart Sound	24-bit	Same
	Accelerometer	16-bit	Same
Sampling Rate	ECG	200 Hz	Same
	Thoracic Impedance	200 Hz	Same
	Heart Sound	500 Hz	Same
	Accelerometer	50 Hz	Same
Memory	Device	microSD card/16GB	Same
Power supply – battery type	Device	Rechargeable Lithium-Ion	Same
Data Transfer	Device	Bluetooth, Cellular, Wi-Fi	Same
Software Interface	Device	iOS Mobile Application	iOS **or Android OS** Mobile Application and **web browser**

Physical SAU Specification: dimensions	Device	3.3” x 2.40” x 1.03”	Same
Physical SAU Specification: weight	Device	3.3 (ounces)	Same
Electrodes	Device	Integrated into the device	Same
Usage Environment	Device	Healthcare facility or Home environment	Same
Environmental Operating Temperature	Device	5^{o}C to 45^{o}C	Same
Storage Temperature	Device	-20^{o}C to 60^{o}C	Same

10. DISCUSSION OF KEY TECHNICAL DIFFERENCES

10.1. Software Interface

See §8.2 above.

11. PERFORMANCE TESTING

This Special 510(k) omits performance data and verification and validation activities that have not been affected by the product changes to the previously cleared SimpleSENSE System (K201699). Testing for the SimpleSENSE Platform not included in this submission:

- Verification of multiparametric data capture
- Verification of Bluetooth and iPhone connectivity
- Verification of encryption of acquired data
- Battery safety and charging status indication
- Signal Acquisition Unit (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

Additional testing referenced in this Special 510(k) was conducted to establish evidence of safe and effective use of the changed device and to demonstrate performance to design specifications. Testing for the SimpleSENSE Platform referenced in this submission:

- Software verification – addition of Android OS App
- Software verification – addition of SimpleSENSE Web Server
- Firmware requirements verification – new requirements for Android OS compatibility

12. CONCLUSION

Based on the qualitative and quantitative comparative analysis provided here, there are no design specification or technical differences between the SimpleSENSE System (predicate) and the SimpleSENSE Platform (new device) that negatively affect the safety or efficacy of the medical device.