December 8, 2023

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

Re: K232053
Trade/Device Name: SimpleSense-BP, SimpleSense-BP Software Application
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: Class II
Product Code: DXN, DXH, DSB, BZQ, DPS, DQD
Dated: July 10, 2023
Received: July 11, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Robert T. Kazmierski -S

for

LCDR Stephen Browning
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)*
K232053

Device Name
SimpleSense-BP

Indications for Use *(Describe)*
The SimpleSense Platform is intended for use at home, a healthcare facility, or medical research organization 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; e) Systolic and Diastolic Blood Pressure and f) 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 with a stationary torso. 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. 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.

The SimpleSense-BP software application is intended to estimate, display and store blood pressure data on adult patients who are twenty two (22) years and older. The SimpleSense-BP can be used after a clinician determines the user's hypertension classification via an auscultatory blood pressure cuff measurement. The Blood Pressure algorithm uses patient specific information (age, gender, height and weight) and the blood pressure measurement as inputs. SimpleSense-BP is used to provide blood pressure estimations derived from physiological sensors to qualified medical personnel as a complimentary physiological feature for the purposes of assessing a patient's cardiac health and variance.

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: October 11, 2022

2. NEW DEVICE

- Trade Name: SimpleSense-BP
- Common Name: Blood pressure monitor
- Classification Name:
  - System, Measurement, Blood-Pressure, Non-Invasive (21 CFR §870.1130 – Product Code DXN)

3. PRIMARY PREDICATE DEVICE – K212160

Provided all sensors and the majority of functionality has not changed since the prior clearance (no physical changes and 5 of 6 product codes remain the same), Nanowear's prior clearance was selected as the predicate device.

- Trade Name: Nanowear Inc. – SimpleSense Platform
- Common Name: Vital signs monitoring system
- Classification Names:
  - Transmitters and Receivers, Electrocardiograph, Telephone (21 CFR §870.2920 – Product Code: DXH)
  - Plethysmograph, Impedance (21 CFR §870.2770 – Product Code: DSB)
  - Monitor, Breathing Frequency (21 CFR §868.2375 – Product Code: BZQ)
  - Electrocardiograph (21 CFR §870.2340 – Product Code: DPS)
  - Stethoscope, Electronic (21 CFR §870.1875 – Product Code: DQD)

4. SECONDARY PREDICATE DEVICE – K190792

Since the predicate device does not include product code DXN, the following reference device is provided to establish equivalence to a previously cleared medical device for the additional product code. *This device is used to establish similar use of software-based analysis to obtain blood pressure in a multi-parameter system*.

- Trade Name: Biobeat Technologies Ltd. – BB-613 WP
- Common Name: Vital signs monitoring system
- Classification Names:

- Oximeter (21 CFR §870.2920 – Product Code: DQA)
- System, Measurement, Blood-Pressure, Non-Invasive (21 CFR §870.1130 – Product Code DXN)
- Transmitters And Receivers, Physiological Signal, Radiofrequency (21 CFR §868.2910 – Product Code: DRG)

5. INDICATIONS FOR USE

The SimpleSense Platform is intended for use at home, a healthcare facility, or medical research organization 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; e) Systolic and Diastolic Blood Pressure and f) 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 with a stationary torso. 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. 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.

The SimpleSense-BP software application is intended to estimate, display and store blood pressure data on adult patients who are twenty two (22) years and older. The SimpleSense-BP can be used after a clinician determines the user's hypertension classification via an auscultatory blood pressure cuff measurement. The Blood Pressure algorithm uses patient specific information (age, gender, height and weight) and the blood pressure measurement as inputs. SimpleSense-BP is used to provide blood pressure estimations derived from physiological sensors to qualified medical personnel as a complimentary physiological feature for the purposes of assessing a patient's cardiac health and variance.

6. DEVICE DESCRIPTION

The SimpleSense-BP Software Application accesses the physiological parameters like ECG, heart sounds, and thoracic impedance captured by the SimpleSense Device for processing into the vital sign outputs of the product which includes estimation of Systolic and Diastolic blood pressure. The software uses recorded data from the SimpleSense electronics module as inputs into a validated computational model for estimating blood pressure over the period of wear. The system samples blood pressure while the user is at rest. In addition, SimpleSense-BP Software utilizes inputs such as demographic information (age, weight, height, and gender) and a blood pressure measurement for clinical stratification to the algorithm. The blood pressure outputs are returned to the SimpleSense Mobile Application and/or SimpleSense webserver for display, review and interpretation by a physician.

The Nanowear SimpleSense system is a non-invasive, wearable, and portable medical device for the evaluation and monitoring of patients. It utilizes physiologic and biometric sensors embedded in a garment and an electronics module to gather the heart health data.

The specific physiological parameters recorded by the device include: two vectors of Electrocardiogram (ECG), respiratory rate though thoracic impedance, heart sounds, and activity including posture. The signals are recorded by the electronics module on a removable data storage card and are periodically transferred to a smartphone mobile application that connects to the electronics module over a wireless Bluetooth connection. The mobile application provides the functionality of transferring the data collected by the electronics module then relaying the data to the Nanowear web server for display of the data by a physician.

7. INTENDED USE

The Nanowear SimpleSense-BP blood pressure software module is intended to estimate systolic and diastolic blood pressure using the SimpleSense device data and demographic information of the patient inclusive of age, weight, height, and gender. In addition, an initial blood pressure value for clinical stratification must be determined and entered by a clinician. The blood pressure value is also input into the device as an input to the blood pressure algorithm. A new blood pressure measurement needs to be taken and updated into the system every 21 days.

8. CLINICAL USE MODEL

The SimpleSense-BP software application allows medical professionals to remotely obtain, and review blood pressure measurements computed from the SimpleSense device data. Under the care of a physician, a medical professional prescribes the SimpleSense device which captures data via the garment, stores and transmits data from a Signal Acquisition Unit (SAU) to a smartphone device via Bluetooth and wirelessly transmits via Wi-Fi or cellular data for review by a medical professional. The data that is transmitted to the Nanowear servers is used as inputs to the SimpleSense-BP software algorithm. The output of the algorithm is estimated Systolic and Diastolic blood pressure.

9. SUBSTANTIAL EQUIVALENCE COMPARISON

See §4 (Indications for Use) above to review **bold** font that demarks the difference between the predicate device and the SimpleSense-BP software.

The table below delineates the differences between the cleared SimpleSense Platform, and the proposed SimpleSense-BP software algorithm. 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 Platform	Nanowear Inc. SimpleSense-BP (on SimpleSense Platform)	BioBeat Technologies LTD BB-613
510(k) Number	**K212160**	**New Device – K214069**	**K190792**
Indications for Use Statement	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.	The SimpleSense Platform is intended for use at home, a healthcare facility, or medical research organization 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; e) Systolic and Diastolic Blood Pressure and f) 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 with a stationary torso. 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. 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. The SimpleSense-BP software application is intended to estimate, display and store blood pressure data on adult patients who are twenty two (22) years and older. The SimpleSense-BP can be used after a clinician determines the user's hypertension classification via a FDA cleared blood pressure cuff and enters patient specific information (age, gender, height and weight). SimpleSense-BP is used to provide blood pressure calculations derived from physiological sensors to qualified medical personnel as a complimentary physiological feature for the purposes of assessing a patient's cardiac health and variance.	The BB-613 WP is a wrist-worn or skin attached device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate. The BB-613WP can also track changes in blood pressure based on Pulse Wave Transit Time (PWTT) which is obtained utilizing pulse measurements from the integrated SpO2 sensor, following a calibration process using oscillometric blood pressure monitor. The BB-613WP is intended for spot-checking of adult patients in hospitals, clinics, long-term care, and home use.
Product Code	DXH, DSB, BZQ, DPS, DQD	DXH, DSB, BZQ, DPS, DQD, DXN	DXN, DQA, DRG
Acquired Data	● Electrocardiogram ● Respiration Rate from thoracic impedance ● Heart Sounds ● Activity	● Electrocardiogram ● Respiration Rate from thoracic impedance ● Heart Sounds ● Activity ● Systolic and Diastolic Blood Pressure from a combination of above data and patient information	● Oxygen Saturation (SpO2) ● Pulse Rate (PR) ● Blood Pressure (BP)
Target Population	Adult patients requiring evaluation of physiologic signals	No change – Same	Adults

	Nanowear Inc. SimpleSense Platform	Nanowear Inc. SimpleSense-BP (on SimpleSense Platform)	BioBeat Technologies LTD BB-613
510(k) Number	**K212160**	**New Device – K214069**	**K190792**
Monitoring Type	● Intermittent, Spot-checking	No change - Same	Spot-checking
Sensor Technology	● Electrocardiogram: Textile-based nanosensors ● Respiration Rate: Textile-based nanosensors measure thoracic impedance and respiration is derived from thoracic impedance ● Heart Sound: Microelectromechanical (MEMs) microphone	No change – Same	Pulse reflectance technology, Four LED (red + IR) and photo diode absorbs reflected light. [Photoplethysmography PPG sensor]
Anatomical Sites	Chest worn sash with multiple embedded sensors	No change – Same	Wrist worn device or adhesive patch on chest
Materials	Polyester, ABS Hook and Loop, Neoprene, Spandex, Silver and Polyurethane	No change – Same The materials used in Nanowear hardware have been consistent across all Nanowear products, including this 510(k) for the SimpleSense-BP. The SimpleSense system hardware (K201669) was used for validating the SimpleSense-BP software and is the exclusive hardware to be used with SimpleSense-BP software.	Polycarbonate, Photodiode window, Silicone Adhesive patch
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.	● 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. ● Blood Pressure: software algorithm model for estimating systolic and diastolic blood pressure based on SimpleSense device data.	● Pulse Wave Transit Time (PWTT) calculation based on measurement of functional oxygen saturation
Display Type	No on-device display Software application for iOS and Android	No change – Same	LCD on device or handheld display unit

	Nanowear Inc. SimpleSense Platform		Nanowear Inc. SimpleSense-BP (on SimpleSense Platform)	BioBeat Technologies LTD BB-613
510(k) Number	**K212160**		**New Device – K214069**	**K190792**
Display Requirement	User provided display hardware for a healthcare professional to view the recorded data. A general-purpose PC/Laptop/Desktop may be used.		No change – Same	N/A
Power Source	Internally powered using Li-Ion rechargeable battery		No change – Same	Internally powered battery
Energy Delivered	No energy delivered		No change – Same	Unknown
Internal Memory	Removeable MicroSD card		No change – Same	On-device storage
Comm. Interface	Wireless transceiver using Bluetooth		No change – Same	Wireless
Access to Recorded Data	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.		No change – Same	Unknown
Use Environment	Home healthcare		No change – Same	Hospitals, clinics, long-term care, and home use
Standards Used	● AAMI ES 60601-1:2005 /(R) 2012 ● IEC 60601-1-6:2010 +A1:2013 ● IEC 60601-1-2:2014 ● IEC 60601-2-47:2012 ● ISO 10993-1:2009 ● ASTM D4169-09 ● ISO 14971:2007		No change – Same	ISO 80601-2-56:2018 IEC 60601-1-2:2014 IEC 60601-1:2012 (3.1 Edition) ANSI C63.27-2017
Sterility	Non-sterile		No change – Same	Supplied and used non-sterile
Photoplethysmography Sensor Attributes	N/A		N/A	Emitted light peak wavelength: 880nm (IR), 650nm (Red) Measurement Range SpO2: 40% to 100% A_{rms}, SpO2: ±2%
Frequency Response	ECG	0.05 Hz - 65 Hz	No change – Same	N/A
	Thoracic Impedance	0.05 Hz - 65 Hz	No change – Same	Unknown
	Heart Sound	0.05 Hz - 236 Hz	No change – Same	N/A
	Accelerometer	0-25 Hz	No change – Same	N/A
Channels	ECG	2 channels	No change – Same	N/A

	Nanowear Inc. SimpleSense Platform		Nanowear Inc. SimpleSense-BP (on SimpleSense Platform)	BioBeat Technologies LTD BB-613
510(k) Number	**K212160**		**New Device – K214069**	**K190792**
	Thoracic Impedance	2 channels	No change – Same	Unknown
	Heart Sound	1 channel	No change – Same	N/A
	Accelerometer	1 channel	No change – Same	N/A
Resolution	ECG	24-bit	No change – Same	N/A
	Thoracic Impedance	24-bit	No change – Same	Unknown
	Heart Sound	24-bit	No change – Same	N/A
	Accelerometer	16-bit	No change – Same	N/A
Sampling Rate	ECG	200 Hz	No change – Same	N/A
	Thoracic Impedance	200 Hz	No change – Same	Unknown
	Heart Sound	500 Hz	No change – Same	N/A
	Accelerometer	50 Hz	No change – Same	N/A
Range	Heart Rate or(Pulse Rate)	40 to 250 bpm (Heart Rate from ECG)	No change – Same	40 to 250 bpm, Arms, ±3% (Pulse rate from PPG)
	Blood Pressure	N/A	SBP: 80-230 mmHg DBP: 40-130 mmHg	0 mmHg – 299 mmHg
	Respiration Rate	6-22 breathes per minute (BPM) with accuracy ± 2 BPM	No change – Same	N/A
Blood Pressure Accuracy	Not Available		± 5 mmHg (Mean Difference); ± 8 mmHg (Standard Deviation)	±5 mmHg (Mean error)
Memory	microSD card/16GB		No change – Same	Unknown
Power Supply – Battery Type	Rechargeable Lithium-Ion		No change – Same	Unknown
Operational Time	Up to 15 hours total recording time using a single garment.		No change – Same	72 hours
Data Transfer	Bluetooth, Cellular, Wi-Fi		No change – Same	Bluetooth, Cellular, Wi-Fi
Software Interface	iOS or Android OS Mobile Application and web browser		No change – Same	iOS or Android OS Mobile Application
Physical Specification: Dimensions	3.3” x 2.40” x 1.03”		No change – Same	Unknown and varies based on wrist worn or chest worn device
Physical Specification: Weight	3.3 (ounces)		No change – Same	Unknown and varies based on wrist worn or chest worn device
Electrodes	Integrated into the device		No change – Same	Unknown
Usage Environment	Healthcare facility or home environment		No change – Same	Healthcare facility or home environment
Environmental Operating Temperature	5^{o}C to 45^{o}C		No change – Same	Unknown
Storage Temperature	-20^{o}C to 60^{o}C		No change – Same	Unknown

10. Discussion of Key System Differences

10.1. Indications for Use, Product Code

The legally marketed predicate SimpleSense Platform (K212160) records, displays and stores ECG, Respiration Rate, and Heart Sounds. With the addition of the SimpleSense-BP software, the SimpleSense Platform can display **systolic and diastolic blood pressure**. There are approximately 500 FDA cleared medical blood pressure monitors in the DXN product code (noninvasive blood pressure measurement system), proving it a well-accepted physiologic parameter for 510(k) clearance.

Generally the addition of blood pressure to a multi-parameter monitor does not introduce additional risks. It is common to view vital signs such as ECG, Heart Rate, Respiratory Rate and Blood Pressure within the same device/user-interface. Analogous to all other parameters measured by the SimpleSense device, blood pressure data is reviewed retrospectively so there are no physiologic alarm functions, no automated diagnosis, and no real-time clinical response as a result of monitoring. There are no additional concerns of safe and effective use of the SimpleSense Platform running the SimpleSense-BP software for display of blood pressure alongside existing parameters.

10.2. Acquired Data

The primary difference between SimpleSense-BP software and primary predicate device is the inclusion of blood pressure estimation. The secondary predicate Biobeat BB-613-WP (K190792) is included to provide *an example of a cleared medical device with a similar use of software-based analysis to obtain blood pressure in a multi-parameter system* (as opposed to the traditionally more common oscillometric method). Biobeat uses Pulse Wave Transit Time (PWTT) which is based on an oxygen saturation sensor data, but there are other similar software-based analysis methods such as Pulse Decomposition Analysis (PDA) which uses ECG and tonometry.

Generally, software-based blood pressure measurements have been proven substantially equivalent to a predicate device by adherence to compliance standards and comparison in non-inferiority studies to a legally marketed medical device. Nanowear has followed that same path to prove substantial equivalence. The performance study was performed to compare the SimpleSense-BP to the gold standard.

10.3. Signal Acquisition Method

Blood Pressure reported by the SimpleSense-BP software is derived from existing (unchanged) sensor data obtained by the SimpleSense Platform. The SimpleSense-BP software is an algorithm model for estimating systolic and diastolic blood pressure based on SimpleSense device data. SimpleSense-BP is a fixed algorithm.

The method of signal acquisition from the nanosensors on the SimpleSense garment, does not raise any new questions regarding patient safety compared to the legally marketed SimpleSense Platform (K212160). This change does not introduce new hazards that result in unacceptable risk for the patient or medical professional. Further evaluation of performance is necessary to ensure the SimpleSense-BP software algorithm analysis is as effective as previously cleared medical device (see §10 below).

10.4. Monitoring Type

The conditions described in the labeling for the required period of rest and the posture to be assumed by the user are identical to the instructions provided to patients who might use cuff-based blood pressure cuff at home following the standard of care for at-home self-reported blood pressure estimation. The users are instructed and are aware that blood pressure will be estimated after the stipulated period of rest following an initiation of a recording on the SimpleSense device. Due to the manner of operation of many cuff-based devices, the inflation of the cuff informs the user that a blood pressure is being estimated. However, the SimpleSense device does not provide a physical stimulus of that nature. Instead, the SimpleSense mobile App provides indication that a recording is ongoing. In either condition, the user is aware that a estimation will be taken by the device and are instructed to remain still. In case of device use outside of intended conditions, the SimpleSense-BP software actively rejects data captured if movements are detected by the SimpleSense activity monitoring function. Given this condition of use, instructions provided to the user, and the presence of software mitigations to detect use outside specified intended use, the difference in monitoring type raises no new questions of safety and efficacy.

11. PERFORMANCE TESTING

The ensemble models estimate systolic and diastolic pressures based on features extracted from the input SimpleSense data, and demographics data inclusive of the clinical stratification, an initial blood pressure measurement, age, gender, height, and weight. These inputs need to be updated every 21 days.

Subjects in four categories of hypertension – Normal, Prehypertensive, Stage 1, and Stage 2 hypertension were recruited with at least 21 subjects in each category as per IEEE 1708-2019a standard requirements reflecting the true breadth of the intended population. Blood pressure variations were induced using physical activity and thermal stimulus and the performance was achieved by the SimpleSense-BP algorithm. The auscultatory reference measurements were used to validate the SimpleSense-BP algorithm. Table 2 includes the results of the testing of the validation set. The range of BP tested was 80-230 mmHg for Systolic Blood Pressure and 40-130 mmHg for Diastolic Blood Pressure.

11.1. Induced blood pressure change test

To ensure models operate accurately over a broad range of blood pressures, both within the specified range of the original model chosen by baseline calibration and outside the range of the baseline model, enrollment was done until at least 10 subjects have a change in BP of at least 15 mmHg systolic or 10 mmHg diastolic for each of the 4 models used by the device.

The analysis results in the tables below show performance on all protocol timepoints, protocol timepoints with nominal changes only, and protocol timepoints with significant changes only.

All tables demonstrate that for each type of significant change in systolic and diastolic pressure and for each clinical stratification, there were at least 10 subjects identified. The

performance Mean Difference (MD) and Standard Deviation of Difference (SD) meets the acceptance criteria of ISO 81060-2 in all 16 categories supporting generalizability across the intended population, safely and efficaciously supporting SimpleSense-BP's indications for use. 149 subjects in total were identified. Due to software risk mitigations within SimpleSense-BP that rejects unusable data, 147 subjects had usable data at any protocol time point of change. The accuracy after an induced change has met the acceptance criteria specified in ISO 81060-2 (mean difference no greater than ±5 mmHg with a standard deviation no greater than 8 mmHg).

TABLE 2 PERFORMANCE OF MEASURED CHANGES IN BLOOD PRESSURE

Measurement Type	All Protocol time points (Overall) included			Only protocol time points with nominal changes (SBP Change ≤ ±15 mmHg; DBP Change ≤ ±10 mmHg)		
	Number of Subjects	Results		Number of Subjects	Results	
		MD	SD		MD	SD
Systolic	147	0.09	4.08	147	0.10	3.88
Diastolic	147	0.35	3.32	147	0.46	3.17

Significant Blood Pressure Changes							
Systolic				Diastolic			
Description of Change	Number of Subjects	Averaged		Description of Change	Number of Subjects	Averaged	
		MD	SD			MD	SD
SBP Increase ≥ 15 mmHg	77	-4.65	2.62	DBP Increase ≥ 10 mmHg	73	-2.54	2.98
SBP Decrease ≤ -15 mmHg	72	4.20	2.87	DBP Decrease ≤ -10 mmHg	25	3.36	3.36

11.2. Accuracy over calibration period test

To ensure the device maintains its accuracy for the labeled period of calibration, performance evaluation was performed with measurements at baseline, at the end, and at intermediate time points. Subjects were enrolled following IEEE 1708 specifications of at least 85 subjects and at least 21 subjects in each clinical stratification of Normal, Prehypertension, Stage 1 hypertension, and stage 2 hypertension. 4 measurements after the initial calibration measurement are made for each enrolled subject separated by 7 days to cover an evaluation period of 21 days.

The table below provides a weekly time point performance for SBP And DBP for weeks 1,2,3, and 4 with device calibrated at week 1. The performance Mean Difference (MD) and Standard Deviation of Difference (SD) meets the acceptance criteria of ISO 81060-2 in all 4 categories and in each of the 7-day timepoints. As originally postulated, there is no evidence of drift or divergence irrespective of test condition. For each change type, the performance meets acceptance criteria established by FDA supporting generalizability across the intended population, safely and efficaciously supporting SimpleSense-BP's indication for use. (Total Number of Subjects = 91). The majority of the subjects are hypertensive, mirroring the focus of the validation study's patient population (~74% hypertensive; 67 out of 91

TABLE 3 PERFORMANCE RESULTS FOR BLOOD PRESSURE MEASUREMENTS OVER THE CALIBRATION PERIOD.

BP measurement type	Recording	Number of Subjects	MD (mmHg)	SD (mmHg)
Systolic	Week-1	91	-1.7	5.13
	Week-2	91	-1.71	5.05
	Week-3	91	-0.88	4.94
	Week-4	91	-2.94	4.82
Diastolic	Week-1	91	-0.41	4.19
	Week-2	91	-0.23	4.12
	Week-3	91	0.22	4.05
	Week-4	91	-0.77	3.75

The device accuracy has met the acceptance criteria specified in ISO 81060-2 (mean difference no greater than ± 5 mmHg with standard deviation no greater than 8 mmHg) for 21 days.

In conclusion, the error performance was within the acceptable range for all subgroups based on clinical stratification. Several transitions in clinical stratifications relative to the initial stratification from static readings were observed in the test population and the subjects enrolled in the study had blood pressures that were evenly spread across the range of blood pressures in each clinical stratification.

11.3. Subject demography

A minimum of 21 subjects were included in each of the four stratifications (Normal, Prehypertensive, Stage 1, and Stage 2 hypertension) for test sets as shown in Figure 1 of 03CBT01 – SimpleSense-BP Validation Report Rev D Appendix C.

There was no overlap of subjects between the training and test data sets i.e., none of the measurements from subjects in the training data set were included in the test data set and vice versa.

TABLE 4 DEMOGRAPHICS AND SUBGROUP INFORMATION

		Induced Change Test Population	Calibration Test Population
Demographic Information	**Category**	**Number of Subjects**	
Ethnicity	Asian	17	16
	Black	45	18
	Hispanic	20	11
	White	67	46
Gender	Female	68	39
	Male	81	52
Age	20 - 30 yrs.	19	10
	30 - 40 yrs.	28	14
	40 - 50 yrs.	38	16
	50 - 60 yrs.	32	24
	60 - 70 yrs.	14	13
	70 - 80 yrs.	18	14

In addition to the coverage of categories of hypertension, the requirements of ISO 81060-2 for distribution of blood pressure values were also satisfied as listed in Table 4.

Table 5 Test set blood pressure distribution satisfying ISO 81060-2 Clause 5.1.5

ISO 81060-2 Clause 5.1.5 Blood Pressure Distribution Requirements	Percentages in test data
At least 5 % of the REFERENCE BLOOD PRESSURE readings shall have a SYSTOLIC BLOOD PRESSURE ≤100 mmHg (13,33 kPa).	9.03%
At least 5 % of the REFERENCE BLOOD PRESSURE readings shall have a SYSTOLIC BLOOD PRESSURE ≥160 mmHg (21,33 kPa).	10.13%
At least 20 % of the REFERENCE BLOOD PRESSURE readings shall have a SYSTOLIC BLOOD PRESSURE ≥140 mmHg (18,66 kPa).	32.15%
At least 5 % of the REFERENCE BLOOD PRESSURE readings shall have a DIASTOLIC BLOOD PRESSURE ≤60 mmHg (8,0 kPa).	7.59%

At least 5 % of the REFERENCE BLOOD PRESSURE readings shall have a DIASTOLIC BLOOD PRESSURE ≥100 mmHg (13,33 kPa).	7.26%
At least 20 % of the REFERENCE BLOOD PRESSURE readings shall have a DIASTOLIC BLOOD PRESSURE ≥85 mmHg (11,33 kPa).	29.73%

12. CONCLUSION

Based on the qualitative and quantitative comparative analysis provided here, there are no design specification or technical differences between the cleared SimpleSense Platform running the SimpleSense-BP software (new device) that negatively affect the safety or efficacy of the medical device. The conclusions drawn from the non- clinical and clinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate devices The proposed SimpleSense-BP software running on the SimpleSense Platform is found to be substantially equivalent to the predicate device.