August 2, 2019

DynoSense Corp.
Saeed Azimi
CEO
15166 Los Gatos Blvd
Los Gatos, California 95032

Re: K190090
Trade/Device Name: DynoSense Vital Sign Measuring System
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI, DQA, DPS, FLL, DRT, MNR
Dated: June 27, 2019
Received: July 2, 2019

Dear Saeed Azimi:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190090

Device Name
Dynosense Vital Sign Measuring System

Indications for Use *(Describe)*
The DynoSense Vital Sign Measuring System is intended to record, transfer, store and display of single lead electrocardiography (ECG), heart rate (HR), functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), respiration rate (RR), and oral body temperature (TEMP). The device comes in contact with the patient for approximately 60 seconds at each use. This system is for spot checking and does not have continuous monitoring capability or any alarm features.

This system is intended for patients 18 years and older in the home environment. It is intended for use with patients who are well perfused and during no motion condition.

This system makes no specific diagnosis. The device is for single patient use.

Users with implanted pacemakers and/or implanted cardio-defibrillators (ICDs) are not recommended to use the device.

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

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the DynoSense Vital Sign Measuring System is provided below:

Device Common Name:	Monitor, Physiological, Patient (Without Arrhythmia Detection or Alarms)
Device Trade Name:	DynoSense Vital Sign Measurement System
Applicant:	DynoSense Corp. 15166 Los Gatos Blvd Los Gatos, CA 95032
Contact:	Saeed Azimi CEO DynoSense Corp sazimi@dynosense.com Phone: (650) 397-6105 Fax: (650) 397-6013
Prepared by:	Saeed Azimi DynoSense Corp (650) 397-6013 sazimi@dynosense.com
Date Prepared:	December 24th, 2018
Classification Regulation:	870.2300, Class II
Classification Name:	Cardiac monitor (including cardiotachometer and rate alarm)
Panel:	Cardiovascular
Primary Product Code:	MWI
Secondary Product Codes:	DQA, DPS, FLL, DRT, MNR
Predicate Devices:	Primary: CheckMe Pro Health Monitor (K150869) Secondary: Welch Allyn Spot Vital Signs Monitor (K132808)

Reference Devices:

- ABL-90 FLEX (K120197)
- Fluke ProSim 8 Vital Simulator (K110429)
- Nellcor Bedside SpO_2 Patient Monitoring System (K142865)
- Capnostream20p (K101995)
- Welch Allyn Spot Vital Signs Monitor (K022163)
- MEDI-TRACE(R) 500 ECG ELECTRODE (K945479)
- EDAN PC-ECG SE1010 EKG (K131819)

1. INDICATIONS FOR USE:

"The DynoSense Vital Sign Measuring System is intended to record, transfer, store and display of single lead electrocardiography (ECG), heart rate (HR), functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), respiration rate (RR), and oral body temperature (TEMP). The device comes in contact with the patient for approximately 60 seconds at each use. This system is for spot checking and does not have continuous monitoring capability or any alarm features.

This system is intended for patients 18 years and older in the home environment. It is intended for use with patients who are well perfused and during no motion condition.

This system makes no specific diagnosis. The device is for single patient use.

Users with implanted pacemakers and/or implanted cardio-defibrillators (ICDs) are not recommended to use the device."

2. DEVICE DESCRIPTION:

The **DynoSense Vital Sign Measuring System** is a battery-powered, handheld, personalized single patient use vital sign measuring apparatus. The user must hold the Device with their left hand. Functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) measurements are based on transmittance of light through the index finger. Respiration rate (RR) measurements are based on pressure change at the aperture opening during breathing. Oral temperature (TEMP) is measured via sublingual and lingual contact with the thermometer tip. ECG and heart rate (HR) measurements are obtained via completing an electrical path across the left side of the chest. Vital sign data are communicated to a Bluetooth-capable mobile platform for forwarding to the cloud application for processing and storage.

3. STERILIZATION, SHELF LIFE, CLEANING, REUSE:

The System is delivered and used non-sterile. The System is intended to be single patient-only, and reusable.

4. BIOCOMPATIBILITY:

The System is a surface device and only includes components which are for limited contact (≤ 24h) and are either intact skin-contacting or mucosal membrane-contacting. The materials were tested in accordance with ISO 10993.

5. PERFORMANCE DATA:

The following performance testing was provided to support the substantial equivalence of the subject device:

- **ECG and Heart Rate Measurements**: To validate the ability of the System to produce ECG waveform and heart rate measurements, bench agreement testing as per ISO 60601-2-47:2012. The ECG and Heart Rate algorithm tested according to the requirements of IEC 60601-2-47.
- **SpO_2 Measurements**: To validate the ability of the System to make pulse oximetry measurements, a clinical agreement study was conducted, as per ISO 80601-2-61:2011.
- **Pulse Rate Measurements**: To validate the ability of the System to make pulse rate measurements a bench agreement study between the System and a pulse rate simulator was performed, and clinical agreement study was performed. Both studies were conducted per ISO 80601-2-61:2011.
- **Respiration Rate Measurements**: To validate the ability of the System to calculate a respiration rate, a clinical agreement study was conducted.
- **Temperature Measurements**: To validate temperature measurements, a clinical agreement study was conducted, as per ISO 80601-2-56:2012.
- **Usability**: Testing was conducted to evaluating the ability of laypeople to read and understand the System instructions for use, and subsequently simulate normal use of the System without prior training.

6. SOFTWARE DOCUMENTATION:

Software documentation for a **Moderate** Level of Concern device is provided in support of the System.

7. ELECTRICAL SAFETY TESTING:

The DynoSense Vital Signs Measuring System was evaluated as per ANSI / AAMI 60601-1:2005 + A1:2012, and found to be compliant.

8. ELECTROMAGNETIC COMPATIBILITY TESTING:

The DynoSense Vital Signs Measuring System was evaluated as per IEC 60601-1-2:2014, and found to be compliant.

9. STANDARDS:

Table 1 provides the complete list of standards that are used in the 510(k) to establish device performance and support substantial equivalence:

Table 1: List of Standards

Standard	Title
ISO 10993-1:2009	Biological Evaluation of Medical Devices - Part 1: Evaluation and testing within a risk management process
ISO 10993-5:2009	Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
ISO 10993-10:2010	Biological Evaluation of Medical Devices - Part 10: Tests for irritation and skin sensitization;
ISO 10993-12:2012	Biological Evaluation of Medical Devices - Part 12: Sample preparation and reference materials
AAMI / ANSI 60601-1:2005 + A1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-11: 2015	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
IEC 60601-1-2:2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 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
AAMI / ANSI 60601-2-47:2012	Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
AAMI / ANSI 60601-2-49:2011	Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
ISO 80601-2-56:2012	Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
ISO 80601-2-61:2011	Medical electrical equipment - Particular requirements for basic safety and essential performance of pulse oximeter equipment.

10. SUBSTANTIAL EQUIVALENCE DISCUSSION

The primary predicate device is the CheckMe Pro Health Monitor (cleared under K150869); the secondary predicate device is the Welch Allyn Spot Vital Signs Monitor (cleared under K132808; this device is also a reference device for temperature measurement validation).

Table 2: Technological Comparison, System vs. CheckMe Pro

Technological Comparison				
	Subject Device	**Predicate Device**		**Substantial Equivalence to Predicate device**
510(k) Number	Unknown	K150869		NA
Applicant	DynoSense Corp.	Viatom Technology Co. Ltd.		NA
Device Name	DynoSense Vital Sign Measuring System	Checkme Pro Health Monitor		NA
Classification Regulation	870.2300 – Physiological Patient Monitor	870.2300 – Physiological Patient Monitor		Same
Physiological Parameters Monitored	ECG, HR, SpO_2, **PR, Respiration Rate (RR),** Temperature	ECG, HR, SpO_2, Temperature		Similar
Location	Home	Home and **Hospital**		Subject device only supports Home Use
Rx or OTC	Rx	Rx		Same
Power Supply	Rechargeable Lithium-Polymer battery **210 mAh**	**560mAh** rechargeable lithium-ion polymer battery		Similar
Alarm	No Alarm	No Alarm		Same
Data collection memory	**Essentially unlimited storage in cloud**	**100 measurements storage**		Better
Operating modes	Spot-Check	**Continuous Recording** and Spot-Check		Subject device only supports Spot-check
Comparison of ECG Measurements				
Measured ECG Parameter	ECG waveform, Heart Rate (HR)	ECG waveform, Heart Rate (HR)		Same
ECG Rhythm Classification	Not included	Not included		Same
ECG Lead Type	Single Lead**, 3 Contacts**	**External ECG Cable and Electrodes**	Integrated Single Lead ECG Electrodes	Similar
Input impedance	>10 M Ohm	> 10 M Ohm	> 10 M Ohm	Same

Technological Comparison				
	Subject Device	**Predicate Device**		**Substantial Equivalence to Predicate device**
Input dynamic range	**±300mV**	**±3 mV**	**±3 mV**	Better
Bandwidth	0.67 to 40 Hz	0.05 – 40 Hz	0.67 – 40 Hz	Same
A/D conversion	**24 bit**	**16 bit**		Better
Sampling Rate	500 Hz	500 Hz		Same
Measurement Time	<60 seconds	30 seconds		Similar
Display	Not included	400*240 Dot-matrix LCD display		NA
Input	Dry conductive electrodes	Dry conduction electrodes and/or external auxiliary electrodes		Similar
Heart rate Range	30～250 bpm	30～250 bpm		Same
Heart rate Accuracy	±2 bpm or ± 2%, whichever is larger	±2 bpm or ±2%, whichever is larger		Same
Comparison of SpO2 Measurements				
Display Data	SpO_2, Pulse Rate (PR)	SpO_2, Pulse Rate (PR)		Same
Mode	Spot-Check	**Continuous Recording** and Spot-Check		Subject device supports Spot-check only
Sensor Types	Integrated	Integrated and **external**		Subject device supports integrated sensor only
Population	Patients ≥18 years of age	Adult and **Pediatric** (continuous recording only for adult)		Subject device supports patients ≥18 years of age
SpO2 Display Range	0% to 100%	0 - 100%		Same
SpO2 Accuracy	70%-100% ±2%	70%-100% ±3%	70%-100% ±2%	Similar
SpO2 Resolution	1 %	1 %		Same
PR range	30-250 bpm	30-250 BPM		Same
PR Accuracy	±2 bpm or ±2%, whichever is greater	±2 bpm or ±2%, whichever is greater		Same
PR Resolution	1 bpm	1 bpm		Same
Comparison of Temperature Measurement and Analysis				
Measurement Technique	Thermo-resistive sensor	**infrared sensor (thermopile)**		Same

Technological Comparison			
	Subject Device	**Predicate Device**	**Substantial Equivalence to Predicate device**
Measurement site	Oral	**Forehead**	Subject device only supports Oral
Mode	Predictive (Normal) Mode	**Direct (Monitor)** Mode	Subject device only supports Predictive (Normal) mode
Unit	°C/°F	°F	Subject device only supports °F
Measuring range	30.0° C – 43.0 ° C	**33.8** ° C **– 42.2** ° C **(93.2°F to 108.0°F)**	Subject device supports wider range
Calibration Accuracy	± 0.2° C (Adjusted mode)	± 0.2° C (±0.4°F)	Similar

Table 3: Technological Comparison, System vs. Welch Allyn Connex Vital Signs Monitor

Comparison of Respiration Rate Measurement			
510(k) Number	Unknown	K132808	NA
Applicant	DynoSense Corp.	Welch Allyn, Inc.	NA
Device Name	DynoSense Vital Sign Measuring System	Connex Vital Signs Monitor	NA
Classification Regulation	870.2300 – Physiological Patient Monitor	870.2300 – Physiological Patient Monitor	NA
Location	Oral	Oral	Same
Measurement Technique	Pressure based	Partial pressure-based	Similar
Location	Home	**Hospital**	Testing conducted on the System supports home use
Display Range	4 bpm – **50 bpm**	4 bpm – **70 bpm**	System supports narrower range
Measurement Range	**4 bpm – 50 bpm**	**6 bpm – 45 bpm**	Better
Accuracy	± 1.5 bpm, or ± 4%, whichever is greater	± 1.5 bpm, or ± 4%, whichever is greater	Same

11. SUBSTANTIAL EQUIVALENCE CONCLUSION

Based on the detailed comparison of specifications to the previously cleared CheckMe Pro Health Monitor (K150869) and the Welch Allyn device (K132808), the functional, performance and clinical testing and conformance with applicable standards as well as the comparison of

indications, the differences do not raise new questions of safety and effectiveness and the DynoSense Vital Signs Measuring System can be found substantially equivalent to the predicate device.