February 21, 2020

Zynex Medical, Inc.
Thomas Sandgaard
CEO
9995 Maroon Circle
Englewood, Colorado 80112

Re: K191697
Trade/Device Name: Cardiac Monitor 1500
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance Plethysmograph
Regulatory Class: Class II
Product Code: DSB, DQA, FLL
Dated: January 21, 2020
Received: January 27, 2020

Dear Thomas Sandgaard:

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

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)*
K191697

Device Name
CM-1500

Indications for Use *(Describe)*
Monitoring of the following parameters and their relative changes, indicative of relative changes in fluid volume in adult patients.

- Bioelectrical Impedance
- Heart Rate
- ECG Amplitude
- PPG Amplitude

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
Cardiac Monitor, Model 1500

This 510(k) summary is being submitted in accordance with the requirements of SMDA and 21CFR § 807.92.

1. Submitter's Information

Submitted by: Zynex Medical Inc.
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Operator Number: 9028838
Registration number: 1723686

Contact person: Thomas Sandgaard
CEO
Phone number: +1-800-495-6670
E-mail: tsandgaard@zynex.com

2. Device Information

Trade name: Cardiac Monitor, Model 1500

Common name(s)

Impedance cardiograph (ICG)

Electrocardiograph (ECG)

Photoplethysmograph (PPG)

Classification name: See Table 1

Device class: II

Table 1, Classification Name

Classification Name	21 CFR Section	Product Code	Product Code Type
Plethysmograph, impedance	870.2770	DSB	Major
Oximeter	870.2700	DQA	Minor
Thermometer, electronic, clinical	880.2910	FLL	Minor

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3. Predicate Devices

The Cardiac Monitor, Model 1500, is substantially equivalent in design (methodology) and indications for use to the predicate devices shown in Table.

Table 2, Predicate Devices

Device Name	Manufacturer	510(k)
BioZ.com System	CardioDynamics International Corporation	K974725
Wrist Ox2 3150	Nonin Medical, Inc.	K102350
TemporalScanner Thermometer	Exergen Corp.	K011291

4. Description

Cardiac Monitor, Model 1500 and accessories monitor a patient's parameters. These parameters include: Bioelectrical Impedance, Heart Rate, ECG Amplitude, PPG Amplitude, and Skin Temperature.

The Cardiac Monitor, Model 1500, is intended to be used in a professional medical environment such as hospitals, clinics and research institutions. The Cardiac Monitor, Model 1500, is a standalone device intended for desktop use. Measurements are to be performed under uninterrupted patient surveillance by the operator.

The user of the Cardiac Monitor, Model 1500, shall be a qualified operator. The operator shall have knowledge of the system and data interpretation, obtained via medical education, system manuals and/or specific courses. The device does not report any diagnosis but provides numerical values. It is the physician's responsibility to make proper judgments based on these numbers.

5. Indications for use

Monitoring of the following parameters and their relative changes, indicative of relative changes in fluid volume in adult patients.

- Bioelectrical Impedance
- Heart Rate
- ECG Amplitude
- PPG Amplitude

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6. Intended Use

Cardiac Monitor, Model 1500 (CM-1500) continuously monitors a patient's physiological parameters. These parameters include: Bioelectrical Impedance, Heart Rate, Electrocardiogram (ECG) Amplitude, Photoplethysmography (PPG) Amplitude, and Skin Temperature.

The CM-1500 is intended to be used in a professional medical environment, i.e. hospitals, clinics and research institutions. The CM-1500 is a standalone device intended for desk-top use. Operation is to be performed as uninterrupted patient surveillance by the operator.

The end-user of the CM-1500 shall be a qualified operator. The operator shall have knowledge of the system and data interpretation, obtained via medical education, system manuals and/or specific courses. The device does not report any diagnosis, but provides numerical values. It is the physician's responsibility to make proper judgments based on these numbers.

IMPORTANT: This device must be ordered or prescribed by a licensed physician.

7. Summary of Technical Comparison with Predicate Devices

The Cardiac Monitor, Model 1500, is a combination of the BioZ.com System, the Wrist Ox2 3150 pulse oximeter, and the TemporalScanner Thermometer sensor predicate devices.

As with the BioZ.com System predicate device, the Cardiac Monitor, Model 1500, is indicated for use as a non-invasive monitor. The Cardiac Monitor, Model 1500, provides real-time and on-line monitoring and trending of parameters, just as the BioZ.com System device.

The BioZ.com System has a similar design, and similar methodology as the Cardiac Monitor, Model 1500, Non-Invasive Monitor. The predicate BioZ.com System, provides a similar non-invasive display and measurement of impedance, electrocardiograph (ECG), and pulse rate monitoring as the Cardiac Monitor, Model 1500.

The impedance cardiography (ICG) and electrocardiography (ECG) sections of Cardiac Monitor, Model 1500, consists of similar architecture as the BioZ.com System.

As with the Wrist Ox2 3150, the Cardiac Monitor, Model 1500, is indicated for use as a non-invasive pulse rate monitor. The Cardiac Monitor, Model 1500, is used to provide real-time and on-line monitoring and trending of pulse rate just as with the Wrist Ox2 3150 device.

For pulse rate monitoring, the Wrist Ox2 3150 has the similar indications for use, has similar design, and similar methodology as the Cardiac Monitor, Model 1500, Non-Invasive Monitor. The predicate Wrist Ox2 3150 provides the same non-invasive display and measurement of pulse rate as the Cardiac Monitor, Model 1500.

The photoplethysmography section of The Cardiac Monitor, Model 1500, consists of a similar device architecture as the Wrist Ox2 3150.

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As with the TemporalScanner Thermometer, the Cardiac Monitor, Model 1500, is indicated for use as a continuous skin temperature monitor. The Cardiac Monitor, Model 1500, is used to provide real-time and on-line monitoring and trending of skin temperature just as the TemporalScanner Thermometer device.

For skin temperature monitoring, the TemporalScanner Thermometer has similar indications for use, has similar design, and similar methodology as the Cardiac Monitor, Model 1500. The predicate TemporalScanner Thermometer provides the same non-invasive monitoring and measurement of skin temperature as the Cardiac Monitor, Model 1500.

The temperature section of the Cardiac Monitor, Model 1500, consists of the same device architecture as the TemporalScanner Thermometer.

8. Non-Clinical Performance Data for Substantial Equivalence Determination

Cardiac Monitor, Model 1500, will be in compliance with the medical device safety standards shown in Table 3.

Table 3, Medical Device Standards Compliance

Standard Number	Standard Name
IEC 60601-1:2005+AMD1:2012 CSV	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
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
ISO 14971:2012	Medical devices - Risk management - Application of risk management to medical devices
ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing

The data provided demonstrates that the Cardiac Monitor, Model 1500, met all applicable requirements and that it is substantially equivalent to the combination of its predicates BioZ.com System, Wrist Ox2 3150, and TemporalScanner Thermometer.

9. Conclusion

On basis of the information above, it is concluded that the device is as safe, as effective, and performs as well as or better than the predicate devices.