June 16, 2023

Zynex Medical, Inc.
Donald Gregg
Zynex Monitoring Solutions
9555 Maroon Circle
Englewood, Colorado 80112

Re: K223217
Trade/Device Name: Zynex Monitoring System, Model CM-1600
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance Plethysmograph
Regulatory Class: Class II
Product Code: DSB, DQA
Dated: December 5, 2022
Received: December 6, 2022

Dear Donald Gregg:

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,

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)*
K223217

Device Name
Zynex Monitoring System, Model CM-1600

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
- ECG Amplitude
- PPG Amplitude
- Skin Temperature

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
Zynex Monitoring System, Model CM-1600

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 Monitoring Solutions, Inc.
9555 Maroon Circle
Englewood, CO 80112 USA

Phone number: +1-800-495-6670
Fax Number: +1-866-870-4089

Contact person: Donald Gregg
President, Zynex Monitoring Solutions
Phone number: +1-800-495-6670
E-mail: dgregg@zynex.com

Date of Summary: 07-October-2022

2. Device Information

Trade name: Zynex Monitoring System, Model CM-1600

Common name(s): Impedance cardiograph (ICG)
Electrocardiograph (ECG)
Photoplethysmograph (PPG)

Classification name: See Table 1

Device class: Class II

Table 1. Classification Name

Classification Name	21 CFR Section	Product Code
Plethysmograph, Impedance	870.2770	DSB
Oximeter	870.2700	DQA
Thermometer, Electronic, Clinical	880.2910	FLL
Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms)	870.2300	MWI

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3. Predicate Devices

The Zynex Monitoring System, Model CM-1600, is substantially equivalent in design (methodology) and indications for use to the predicate device shown in Table 2.

Table 2. Predicate Device

Device Name	Manufacturer	510(k)
Cardiac Monitor, Model 1500 (CM-1500)	Zynex Medical, Inc.	K191697

4. Description

Patient monitoring with the CM-1600 is intended to provide data to clinicians, doctors, and post-operative care providers. Accurate diagnostic tools and continuous data monitoring systems are valuable additions for anesthesiologists and surgeons through improving post-operative outcomes and provider confidence. The CM-1600 System is comprised of two (2) subsystems, the Wearable and the Monitor. The CM-1600 Wearable is designed and developed by Zynex Monitoring Solutions, and it collects physiological parameters and transmits those parameters to the CM-1600 Monitor via wireless communication. The CM-1600 Monitor is a Zynex-branded, third-party all-in-one medical grade tablet.

The Zynex Monitoring System, Model CM-1600, simultaneously monitors various parameters of a patient's body. These parameters include Bioelectrical Impedance, Electrocardiogram (ECG) Amplitude, Photoplethysmography (PPG) Amplitude, and Skin Temperature. A Relative Index value is calculated as a combination of the changes in these parameters and is represented by a single number.

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
- ECG Amplitude
- PPG Amplitude
- Skin Temperature

6. Intended Use

The Zynex Monitoring System, Model CM-1600 continuously monitors a patient's physiological parameters. These parameters include Bioelectrical Impedance, Electrocardiogram (ECG) Amplitude, Photoplethysmography (PPG) Amplitude, and Skin Temperature.

This device is intended to be used in a professional medical environment (e.g., hospitals, clinics, and

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research institutions). The CM-1600 is a standalone device intended for desktop or mounted use (e.g., mounted to an IV pole), where operation is to be performed as uninterrupted patient monitoring.

The CM-1600 shall only be used by a qualified operator. The operator shall have knowledge of the system and data interpretation obtained via medical education, system documentation, and/or specific training. The device does not report any diagnosis but provides numerical values to aid the diagnosis by a physician; it is the physician's responsibility to make proper judgements based on these measurements.

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

7. Summary of Technical Comparison with Predicate Device(s)

The Zynex Monitoring System, Model CM-1600 is a wireless version of the CM-1500, which monitors the same physiological and is indicated for use as a noninvasive monitor.

The CM-1600 features similar technology and techniques of obtaining physiological data as the CM-1500. The impedance cardiography (ICG) and electrocardiography (ECG) sections of the CM-1600 consist of similar architecture as the Cardiac Monitor, Model 1500. Both devices capture these signals with identical surface electrodes. For skin temperature monitoring, the Zynex Monitoring System, Model CM-1600, has identical indications for use, methodology, and processing as the Cardiac Monitor, Model 1500. For plethysmography amplitude monitoring the Zynex Monitoring System, Model CM-1600, method of measuring plethysmograph signal is reflective photoplethysmography on the bottom of the Wearable, whereas the Cardiac Monitor, Model CM-1500 used transmissive technology. For plethysmography amplitude monitoring, the CM-1600 has identical indications for use and similar processing as that of the predicate.

The basic elements of the UI (e.g., Relative Index™ trend graph, PPG waveform, and parameter pane locations) are identical between the Zynex Monitoring System, Model CM-1600 and the predicate.

8. Performance Data

The following performance data were provided in support of substantial equivalence determination:

Table 3. Performance test names, criteria, and results for the CM-1600.

Test Name	Testing Criteria	Test Results (Pass/Fail)
Biocompatibility	ISO 10993	Pass
Device Safety, Electrical Safety, and Electromagnetic Compatibility (EMC)	IEC 60601-1 and 60601-1-2	Pass
Wireless Coexistence Testing	AAAMI-TIR63	Pass
Animal Testing	N/A	N/A
Clinical Testing	N/A	N/A
Performance Testing	V&V/Predicate Testing	Pass

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Biocompatibility Testing

The biocompatibility evaluation of the CM-1600 was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

Device Safety, Electrical safety, and electromagnetic compatibility (EMC)

Mechanical safety, Electrical safety and EMC testing were conducted on the CM-1600, consisting of the Wearable, Monitor, and Charging Station. The system complies with the IEC 60601-1 standard and the IEC 60601-1-2 standard for EMC.

Animal Testing: No Testing Required.

Clinical Testing: No Testing Required.

Table 4. Medical Device Standards Compliance (full list in Section 9)

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 14971:2019	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 from the performance testing demonstrates that the Zynex Monitoring System, Model CM-1600 meets all applicable requirements and is substantially equivalent to the predicate device, the Zynex Monitoring Solutions Cardiac Monitor, Model 1500 (CM-1500).

9. Conclusion

The CM-1600 device is as safe and as effective as the predicate device, the CM-1500, when considering device indication for use, performance, safety, EMC, biocompatibility, and other data presented above. Therefore, the CM-1600 is substantially equivalent to the predicate device. Any minor differences between the subject and predicate devices do not raise any different safety or effectiveness concerns with the subject device.