DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 17, 2016

Axeo Medical Technologies, LLC
Stamatios Parimeros
President
971 Virginia Avenue
Suite A
Palm Harbor, Florida 34683

Re: K153079
Trade/Device Name: Axeo 3 Patient Monitor
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI, DPS, DXN, DQA, BZQ, FLL
Dated: February 12, 2016
Received: February 16, 2016

Dear Stamatios Parimeros:

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. 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.

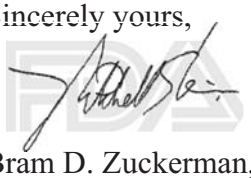
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153079

Device Name

AXEO 3 Patient Monitor

Indications for Use *(Describe)*
The purpose and function of the AXEO 3 patient monitor is to monitor basic physiological parameters including

- ECG waveform derived from 3 or 5 lead measurements
- Heart Rate
- NIBP (systolic, diastolic, and mean arterial pressure)
- SpO2
- Respiration
- Temperature – up to 2 channels (Dual Temperature)

The target population is for adult, neonate and pediatric patients. It may be used as bedside or portable monitor and be used in all hospitals and hospital-type facilities such as clinics and emergency room facilities. It is to be used under the direct supervision of a licensed healthcare practitioner.

This device is not intended for use as an apnea monitor.

Prescription Use: Federal law restricts this device to sale by or on the order of a physician.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

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510(k) Summary

(as required by 21 CFR 807.92)

SUBMITTER OF 510(k) AND REGULATORY CORRESPONDENT

Axeo Medical Technologies, LLC
971 Virginia Avenue, Suite A
Palm Harbor, FL 34683
Phone: 727-787-2936
FAX: 727-787-2398
Contact Person: Stamatios Parimeros, President
Email: axeomedical3@gmail.com

Date prepared: March 16, 2016

DEVICE

Trade/Proprietary Name: Axeo 3 Patient Monitor
Common Name: Patient Physiological Monitor (without arrhythmia detection or alarms)
Classification Name: Monitor, physiological, patient (without arrhythmia detection or alarms)
Device Panel: Cardiovascular
Device Class: Class II
Classification Regulation Number: 21 CFR 870.2300
Product Code: MWI

Subsequent Product Codes:

Regulation Number	Name	Product Code
870.2340	Electrocardiograph	DPS
870.1130	Non-invasive Blood Pressure Measurement	DXN
870.2700	Oximeter	DQA
868.2375	Breathing frequency monitor	BZQ
880.2910	Clinical Electronic Thermometer	FLL

PREDICATE DEVICES

The Axeo 3 Patient Monitor is substantially equivalent in intended use and similar technological characteristics of ECG, Heart Rate, NIBP, SpO_2, Respiration, and Temperature as the Omni II Patient Monitor which is one of the monitors cleared as part of K132229, Omni Patient Monitor (models: Omni, Omni II, Omni III, and Omni Express). The Axeo 3 Patient Monitor is also substantially equivalent in intended use and similar technological characteristics of ECG, Heart Rate, NIBP, SpO_2, Respiration,

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and Temperature as the Omni II Patient Monitor which was cleared in K103737, Omni II Patient Monitor.

These predicates have not been subject to design-related recalls.
No reference devices were used in this submission.

DEVICE DESCRIPTION

The Axeo 3 Patient Monitor is a comprehensive monitoring system with up to 8 traces compiling, processing, analyzing, and displaying data from up to six different patient parameters: ECG, Heart Rate, NIBP, SpO_2, Respiration, and Temperature. It integrates parameter measuring modules, a display, and a recorder in one device, featuring compactness, light weight, and portability.
A built-in rechargeable battery facilitates off-AC-power transport of the patient providing at least four hours of monitoring from a fully charged battery. The battery recharges when AC power is reconnected to the monitor.
The associated accessories include:

- ECG Cable
- SpO2 Finger Probes
- Blood Pressure Cuffs
- Temperature Probe
- Power Supply with Power Cord
- User's Manual

INTENDED USE AND INDICATIONS FOR USE

The purpose and function of the Axeo 3 patient monitor is to monitor basic physiological parameters including

- ECG waveform derived from 3 or 5 lead measurements
- Heart Rate
- NIBP (systolic, diastolic, and mean arterial pressure)
- SpO_2
- Respiration
- Temperature – up to 2 channels (Dual Temperature)

The target population is for adult, neonate and pediatric patients.

It may be used as bedside or portable monitor and be used in all hospitals and hospital-type facilities such as clinics and emergency room facilities. It is to be used under the direct supervision of a licensed healthcare practitioner.

This device is not intended for use as an apnea monitor.

Prescription Use: Federal law restricts this device to sale by or on the order of a physician.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The monitoring of basic physiological parameters is the technological principle for the predicate devices and the proposed device. It is based on the use of accessories that are connected externally to the monitors in order to monitor a specific physiological parameter. At a high level, the predicate devices and the proposed device are based upon the same technological characteristics:

- Energy Source
- The monitoring of ECG
- The monitoring of Heart Rate
- The monitoring of Non-invasive Blood Pressure
- The monitoring of SpO_2

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- The monitoring of Respiration
- The monitoring of Temperature
- Touchscreen Technology
- Software

The following technological differences exist between the predicate devices and the proposed device:

- Optional SpO_2
- Optional IBP
- Optional sidestream or mainstream CO2 module
- Optional sidestream or mainstream Anesthetic Agents module
- Optional Networking
- Optional VGA output
- Physical Dimensions
- Weight

Reason for Submission:
Axeo Medical Technologies intends to market the Axeo 3 Patient Monitor.

PERFORMANCE DATA

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

Biocompatibility Testing

The accessory contact materials utilized by the Axeo 3 Patient Monitor have been well characterized chemically and physically and have a long history of safe use in predicate devices and are categorized as Generally Regarded as Safe (GRAS).

In addition, all patient contact components have been FDA cleared through the 510(k) Premarket Notification process and have been tested for biocompatibility.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the Axeo 3 Patient Monitor, its accessories of power cord, power supply, NIBP reusable adult, pediatric, and neonate cuffs, SpO2 reusable adult finger sensor, SpO2 reusable neonate wrap sensor, ECG reusable cable, and Temperature reusable probe The system complies with the IEC60601-1 standards for safety and the IEC60601-1-2 standard for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical devices”. The software for this device was considered as a “Moderate” level of concern, since a failure or latent flaw could directly result in minor injury to the patient or operator.

Performance Testing

- ECG Performance Test
- Alarm Performance Test
- Multifunction Patient Monitor Performance
- SpO2 Performance Test
- NIBP Performance Test
- Temperature Performance Test
- Battery Performance Test

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Summary of Non-Clinical Data

The Axeo 3 Patient Monitor underwent tests according to several different performance standards as well as on-battery operating and recharge time testing. Below is a chart of the different testing that was completed.

Performance Test	Standard of Compliance
Safety and Performance	AAMI/ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text)
EMC Safety and Performance	IEC 60601-1-2 Edition 4.0 2014-02
ECG Safety and Performance	IEC 60601-2-27 Edition 3.0 2011-03
Alarm Systems Safety and Performance	IEC 60601-1- 8: 2006 (Second Edition) + Am.1: 2012 for use in conjunction with IEC 60601-1: 2005 (Third Edition) + Am.1: 2012
Multifunction Patient Monitoring Safety and Performance	IEC 60601-2-49 (Second Edition): 2011
SPO2 Safety and Performance	ISO 80601-2-61 First edition 2011-04-01
NIBP Safety and Performance	IEC 80601-2-30 Edition 1.1 2013-07
TEMP Safety and Performance	ISO 80601-2-56:2009 (First Edition) for use in conjunction with IEC 60601-1:2005 (Third Edition)

CONCLUSIONS

The completed testing demonstrates that the Axeo 3 Patient Monitor has the same intended use and similar mechanical, functional, and technological characteristics as the predicate devices in addition to the patient contact accessories being acceptably biocompatible. In other words, the described engineering differences between the Axeo 3 Patient Monitor and the predicate devices do not affect either the intended use or the underlying technology of the device. We believe that there are no new safety or effectiveness issues introduced by the engineering differences concerning this device.

Based upon those characteristics and the conclusions of each of the Axeo 3 Patient Monitor bench tests it is determined that the Axeo 3 Patient Monitor is substantially equivalent to the predicate devices, safe and effective, and intended for the same uses.