510(k) Summary

JUL 2 3 2013

Company: Zoe Medical, Inc.
460 Boston Street
Topsfield, MA 01983
Phone: (978) 887-1410
FAX: (978) 887-1406

Establishment Registration: 3003294644

Primary Contact: James Chickering
Regulatory Affairs Manager

Date Prepared: March 13, 2013

Trade Name: Zoe Medical Nightingale Monitoring System

Common Name: Patient Physiological Monitor

Classification Name: Monitor, Physiological Patient

Product Code: MWI

Classification Regulation: 21 CFR 870.2300

Device Description

The Zoe Medical Nightingale Monitoring System (NMS) facilitates the monitoring of patient physiological parameters both at the bedside on the Nightingale PPM3 monitor and remotely on the Nightingale MPC central station. The physiological parameters monitored by the NMS include: ECG, impedance respiration, non-invasive blood pressure, invasive blood pressure, body temperature, functional arterial oxygen saturation (SpO_2), and end-tidal & inspired CO_2 (capnography). The Nightingale Monitoring System as described in this submission is a new device, and will be marketed as the next generation product superseding the original and previously cleared Zoe Medical NMS (K001775).

The part numbers for the four Nightingale PPM3 variants and their associated configurations are given below.

179-0003 NIGHTINGALE PPM3 (with NIBP, SPO2, ECG, and Temp)

179-1000 NIGHTINGALE PPM3 WITH IBP (with NIBP, SPO2, ECG, Temp, & IBP)

179-1001 NIGHTINGALE PPM3 WITH ETCO2 (with NIBP, SPO2, ECG, Temp, & Microstream ETCO2)

179-1002 NIGHTINGALE PPM3 (with NIBP, SPO2, ECG, Temp, IBP, & Microstream ETCO2)

The Nightingale MPC central station (171-0001) will be sold as an option available to all customers based on their needs.

Intended Use

The Zoe Medical Nightingale Monitoring System is indicated for use in adult & pediatric patient populations.

The Zoe Medical Nightingale Monitoring System facilitates the monitoring of:

- ECG
- Impedance respiration
- Non-Invasive blood pressure
- Invasive blood pressure
- Body temperature
- Functional arterial oxygen saturation (SpO_2)
- End-tidal & inspired CO_2

The Zoe Medical Nightingale Monitoring System is a prescription device intended to be used by healthcare professionals in all areas of a healthcare facility.

Substantial Equivalence

The Nightingale Monitoring System utilizes the same Zoe Medical and Oridion Medical components utilized in the primary predicate device, the Spacelabs Healthcare *élance* Vital Signs Monitoring System (K090556).

Table 1. Comparison of the Subject and Predicate Devices

Characteristic	Zoe Medical Nightingale Monitoring System (this submission)	Spacelabs Healthcare *élance* Vital Signs Monitoring System (K090556)	Discussion of Differences
Intended Use	The Zoe Medical Nightingale Monitoring System is indicated for use in adult & pediatric patient populations. The Zoe Medical Nightingale Monitoring System facilitates the monitoring of: - ECG - Impedance respiration - Non-Invasive blood pressure - Invasive blood pressure - Body temperature - Functional arterial oxygen saturation (SpO_2) - End-tidal & inspired CO_2 The Zoe Medical Nightingale Monitoring System is a prescription device intended to be used by healthcare professionals in all areas of a healthcare facility.	The Spacelabs *élance* Vital Signs Monitor is indicated for use in patient populations for: - Adult - Pediatric The Spacelabs *élance* Vital Signs Monitor facilitates the monitoring of: - ECG with arrhythmia detection - Respiration - Non-Invasive blood pressures - Invasive blood pressures - Body temperature - Functional arterial oxygen saturation - Expired and/or inspired CO_2 The Spacelabs *élance* Vital Signs Monitor is a prescription device intended to be used by healthcare professionals in all areas of a healthcare facility.	Nightingale not intended for arrhythmia monitoring

Characteristic	Zoe Medical Nightingale Monitoring System (this submission)	Spacelabs Healthcare *élance* Vital Signs Monitoring System (K090556)	Discussion of Differences
Parameters	ECG, impedance respiration, non-invasive blood pressure, invasive blood pressure, body temperature, functional arterial oxygen saturation (SpO_2), end-tidal & inspired CO_2 (Oridion Microstream®).	Same	Optional arrhythmia components not included in Nightingale
Number of Waveforms	3 or 5	Same	
User Interface	Push knob and dedicated keys	Touch screen	PPM3 meets intended use
Alarm Levels	3 per IEC 60601-1-8	Same	
Operating Modes	Continuous	Same	
Trending	72 hours	Same	
Size	286 W x 182 H x 83 D (mm) w/ 8.4" display	252 W x 193 H x 70 D w/ 10.2" display or 291 W x 221 H x 70 D (12.1" display)	PPM3 represents a slimmed down design
Electrical	Medical grade power supply with internal lithium-ion battery	Same	
Equipment Type	Portable, Indoor Use Only	Same	
Ingress Protection	IPX1	Same	
Operating Conditions	0 to 40°C (32 to 104°F) 15 to 90% RH, non-condensing 0 to 4572 m (0 to 15,000')	Same	
Storage Conditions	-20 to 60°C (-4 to 140°F) 15 to 95%, non-condensing 0 to 12192 m (0 to 40,000')	Same	
Electromagnetic Compatibility	Meets IEC 60601-1-2:2007	Same	
Central Station	Support for 64 monitors; Parameters: ECG, Respiration, NIBP, IBP, Temp, SpO_2, $EtCO_2$, $FiCO_2$; Alarming with Logging; Printed Vital Sign, Summary, Trend Reports	Same	

Table 2. Performance Testing of the Nightingale Monitoring System

Category	Testing Summary
Sterilization Validation	The Nightingale Monitoring System is not sterilized or sterilizable, and therefore this section does not apply to the monitor itself.
Shelf Life Testing	The Nightingale Monitoring System does not have a shelf life, and therefore this section does not apply to the monitor itself.
Biocompatibility Testing	The Nightingale Monitoring System has no patient contact materials, and therefore this section does not apply to the monitor itself.
Software Testing	Software for the Nightingale Monitoring System was designed and developed in accordance with Zoe Medical software development processes, and was verified and validated. Test results indicated that the Nightingale Monitoring System complies with its predetermined specification.
Electrical Safety	The Nightingale Monitoring System was tested for patient safety in accordance with the following applicable standards: • AAMI ES 60601-1:2005 • ANSI/AAMI SP10:2002 / A1:2003 • IEC 60601-1-4:2000 • IEC 60601-1-8:2006 • IEC 60601-2-27:2011 • IEC 80601-2-30:2009 • IEC 60601-2-34:2011 • ISO 80601-2-55:2011 • ISO 80601-2-56:2009 • ISO 80601-2-61:2011 • IEC 62366:2007 • IEC 62304:2006 Test results indicated that the Nightingale Monitoring System complies with its predetermined specification.
Electromagnetic Compatibility Testing	The Nightingale Monitoring System was tested for EMC in accordance with IEC 60601-1-2:2007. Test results indicated that the Nightingale Monitoring System complies with its predetermined specification.
Performance Testing – Bench	The Nightingale Monitoring System was tested in accordance with Zoe Medical internal requirements and procedures, and test results indicated that the device complies with the predetermined requirements. This testing includes performance and functional, environmental, and shipping and transportation testing.
Performance Testing – Animal	Animal performance testing was not performed and is not necessary to demonstrate safety and effectiveness of the Nightingale Monitoring System.
Performance Testing - Clinical	Clinical performance testing was not performed and is not necessary to demonstrate safety and effectiveness of the Nightingale Monitoring System.

Conclusion

Based upon a comparison of devices and performance testing results, the Zoe Medical Nightingale Monitoring System is substantially equivalent to the predicate device.

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

July 23, 2013

Zoe Medical, Inc.
c/o Mr. James Chickering
Regulatory Affairs Manager
460 Boston Street
Topsfield, MA 01983

Re: K130740
Trade/Device Name: Nightingale Monitoring System
Regulatory Number: 21 CFR 870.2300
Regulation Name: Physiological Patient Monitor (without arrhythmia detection or alarms)
Regulatory Class: II (two)
Product Code: 74 MWI
Dated: April 21, 2013
Received: April 24, 2013

Dear Mr. Chickering:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K130740

Indications for Use

510(k) Number: _____

Device Name:

Zoe Medical Nightingale Monitoring System

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Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen R. Faris -S
Date: 2013.07.23 16:23:12 -04'00'