December 18, 2019

Mermaid Care A/S
Claus Lindholt
Chief Technology Officer
Hedelund 1
Norresundby, DK DK-0400

Re: K192584
Trade/Device Name: BEACON Caresystem, Model 00002144
Regulation Number: 21 CFR 868.1850
Regulation Name: Monitoring Spirometer
Regulatory Class: Class II
Product Code: BZK
Dated: September 16, 2019
Received: September 19, 2019

Dear Claus Lindholt:

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,

James J. Lee Ph.D.
Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental 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)*

K192584

Device Name

BEACON Caresystem, Model 00002144

Indications for Use *(Describe)*

The intended use of the BEACON Caresystem is to provide

- respiratory mechanics monitoring in adult patients in the Intensive Care Unit (ICU)
- on-demand ventilator-dependent open-loop advice in mechanically ventilated adult patients as prescribed by the clinician

Patients should be hemodynamically stable.

The device is intended for use by properly trained clinicians. BEACON Caresystem is for prescription use, only.

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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

K192584 510(K) SUMMARY

MERMAID CARE

510(k) Summary in accordance with 21 CFR 807.92

Submitted by:	Mermaid Care A/S Hedelund 1 DK-9400 Noerresundby Denmark Tel.: +45 70 23 70 15
Contact Person:	Claus Lindholt, CTO
Date of Summary:	September 16, 2019
Device Trade Name:	BEACON Caresystem, Model 00002144
Common or Usual Name:	Monitoring Spirometer (Product code: BZK)
Classification Name:	Spirometer, Monitoring (W/Wo Alarm) [21 C.F.R. §868.1850]
Class:	II
Predicate Device:	Philips NM3 Respiratory Monitor with VentAssist (K103578)
Reference Device and accessories:	GE Healthcare Datex-Ohmeda S/5TM Compact Airway Module (model family E-CAiOVX) E-CAiOVX, E-CAiOV, E-CAiO, E-COVX, E-COV, E-CO (K051092)

Reference Product Codes:

Code:	Regulatory Description:	Regulation Number:
BZL	Oxygen uptake computer	21 C.F.R. §868.1730
DQA	Oximeter	21 C.F.R. §870.2700
CCK	Carbon dioxide gas analyzer	21 C.F.R. §868.1400
CCL	Oxygen gas analyzer	21 C.F.R. §868.1720

Device Description:

BEACON Caresystem is an Intensive Care Unit (ICU) ventilation assist system. BEACON Caresystem will provide ICU clinicians with on-demand ventilator-dependent open-loop advice for ventilating adult patients.

BEACON Caresystem uses inputs measured by BEACON Caresystem and data inputs from the ventilator and manual data entry by the clinician into a computer program that has been designed to provide advice for changes to the ventilator settings for the individual patient undergoing mechanical ventilation.

BEACON Caresystem is an adjunct to third party legally marketed ICU mechanical ventilators. Currently supported mechanical ventilators are:

- Maquet Servo I [K073179]
- Dräger Evita XL [K083050]
- Dräger Infinity V500 [K093633]
- Puritan Bennett PB840 [K001646]
- Puritan Bennett PB940 [K131252]
- Hamilton G5 [K070513].

BEACON Caresystem consists of the following components:

- BEACON Display Unit
- BEACON Gas Module
- BEACON Power Adaptor
- NONIN XPOD SpO2 Analyzer

BEACON Caresystem utilizes the following cleared accessories:

- BEACON Flow Sensor (Adult) - private label version of Metaphor E-Z Flow Sensor, Size Adult [K093080]
- BEACON Water Trap (Adult) [K182075 & K171292]
- NONIN Finger Clip SpO2 sensor - NONIN 8000AA1 [K071285]
- NONIN Ear Clip SpO_2 sensor- NONIN 8000Q2 [K080255]
- NONIN Forehead Reflectance SpO_2 sensor - NONIN 8000R [K071285]

The BEACON Display Unit is a standard off-the-shelf tablet touch-screen computer. The BEACON display unit connects through a USB port to the NONIN XPOD SpO2 analyzer for pulse oximetry measurements and serial data ports for connection to the BEACON Gas Module and the connected ICU ventilator. The BEACON Display unit includes the BEACON Caresystem Software. The BEACON Gas Module performs measurement of patient airway flow and inspired and expired fractions of CO_2 and O_2 in the airway.

As described above, BEACON Caresystem combines the functionalities of a spirometric monitor, respiratory gas monitor, and pulse oximeter. Each of these functions, respectively, is intended for:

- Respiratory mechanics monitoring (i.e. airway flow/volume)
- Measurement of expired and inspired breathing gases (CO_2, O_2) and respiration rate
- Non-invasive measurement of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate.

The BEACON Caresystem Software utilizes the monitored parameters above with data from the connected ICU ventilator and clinician entered values to generate on demand, open-loop advice for changes to the ventilator settings for an adult patient undergoing mechanical ventilation.

Indications for Use:

The intended use of the BEACON Caresystem is to provide

- respiratory mechanics monitoring in adult patients in the Intensive Care Unit (ICU)
- on-demand ventilator-dependent open-loop advice in mechanically ventilated adult patients as prescribed by the clinician

Patients should be hemodynamically stable.

The device is intended for use by properly trained clinicians. BEACON Caresystem is for prescription use, only.

The Indications for Use statement for the BEACON Caresystem is not identical to the predicate device; however, the differences do not alter the intended clinical use of the device nor do they affect the substantial equivalence to the predicate.

Comparison of the technological characteristics with the Predicate Device and Reference Device:

BEACON Caresystem and the predicate device both continuously measure pulse oximetry, inspiratory and expiratory air flow and gas and provide on-demand advice on ventilator settings based on the patient specific measurements on a display unit.

At a high level, the subject and predicate devices are based on the following same technological elements:

- Pulse oximetry
- Respiratory flow and carbon dioxide gas measurements and signal processing
- Advice generation of mechanical ventilator settings
- Graphical display of measurements and advice for the user

The following technological differences exist between the subject and predicate devices:

- Subject device measures respiratory Oxygen gas fraction
- Subject device requires connection to a supported mechanical ventilator for advice generation, whereas ventilator connectivity is optional in predicate device

The Reference Device has been included to account for the addition of Oxygen measurements in the subject device. The subject and reference devices uses similar measurement technologies and testing has shown comparable performance.

Non-Clinical Performance Tests Submitted:

BEACON Caresystem has been designed and tested for compliance to the following recognized standards:

- IEC 60601-1:2012 Ed. 3.1, Medical electrical equipment-Part1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014, ed.4. Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic compatibility Requirements and tests.
- IEC 80601-2-61:2017 Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.
- AIM Standard 7351731 Rev. 2.00 2017-02-23. Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers
- IEC 62304 Edition 1.1 2015-06, Medical Device Software - Software Life Cycle Processes.
- IEC 62366-1 Edition 1.0 2015-02, Medical Devices - Part 1: Application Of Usability Engineering To Medical Devices [Including Corrigendum 1 (2016)].
- ISTA 3A 2008, Packaged-Products For Parcel Delivery System Shipment 70 Kg (150 Lb) Or Less.

A head-to-head test comparing the advice presented by BEACON and the predicate device was performed on a patient simulator and the results showed that the BEACON advice generation is comparable to the predicate device.

Gas and flow measurements in BEACON has been evaluated in bench test comparisons with predicate and reference devices. End-tidal Carbon Dioxide ($EtCO_2$), Alveolar Ventilation (VA), Respiratory Rate (RR) measurements were tested against the predicate device. Oxygen Uptake (VO_2), Carbon Dioxide Production (VCO_2) and Energy Expenditure (EE) measurements were tested against the reference device. All tests showed that the measurements of BEACON is comparable to the predicate or reference devices in the full ranges specified.

BEACON Caresystem has two patient contacting accessories, which are both FDA-cleared and legally marketed, so no new biocompatibility testing was performed.

Clinical Tests Submitted:

Five clinical studies where the advice generation of BEACON Caresystem were tested have been submitted.

Three studies evaluated the clinical agreement of BEACON Caresystem advice and the effects of the applied advice to the patients' respiration and oxygenation. The studies concluded that BEACON Caresystem generated advice with high clinical practice agreement.

One study evaluated the ability of BEACON Caresystem advice to find appropriate breathing effort levels for spontaneous breathing patients. The reference technique esophageal catheter was used to estimate breathing effort. The study concluded that BEACON Caresystem responded appropriately to over and under support.

The fifth study evaluated blindly the BEACON Caresystem advice and active clinical opinion of clinicians in patient cases.

Conclusion:

The BEACON Caresystem utilizes equivalent technology and has similar technical specifications as the predicate device and the reference device, the Philips NM3 Respiratory Monitor with VentAssist and Reference Device, the GE Healthcare Datex-Ohmeda S/5™ Compact Airway Module (model family E-CAiOVX and accessories), respectively.

The detailed comparison and the submitted non-clinical performance testing and clinical data demonstrate that the BEACON Caresystem performs comparably to the predicate and reference device and is therefore substantially equivalent to the legally marketed predicate device, Philips NM3 Respiratory Monitor with VentAssist [K103578].