DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 15, 2016

PneumaCare Limited
c/o Ms. Nandini Murthy
Regulatory Consultant to PneumaCare
Alacrita, One Broadway, 14th Floor, Kendall Square
Cambridge, Massachusetts 02142

Re: K151940
Trade/Device Name: Thora-3Di, Model T-01
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: BZQ
Dated: February 9, 2016
Received: February 10, 2016

Dear Ms. Nandini Murthy:

This letter corrects our substantially equivalent letter of March 10, 2016.

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 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" (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 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control and Dental 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 on last page

510(k) Number *(if known)*
K151940

Device Name

Thora-3Di, Model T-01

Indications for Use *(Describe)*

The Thora-3Di is intended for a one-time measurement of respiratory rate as part of a vital signs assessment. The device is indicated for hospital or clinical use in adult patients. The device is intended to be operated by clinicians and medically qualified personnel. It is available for sale only upon the order of a physician or licensed health care provider.

The Thora-3Di is not intended to monitor vital signs. This device is not an apnea monitor.

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)*

510(k) SUMMARY

Submitter Name:	PneumaCare Limited
Submitter Address:	Prospect House, 3 St Thomas' Place Cambridgeshire Business Park, Ely CB7 4EX, United Kingdom
Contact Person:	Mark Harwood
Phone Number:	00 44 (0) 1223 967414
Fax Number:	00 44 (0) 1353 666 692
Date Prepared:	10 March 2016
Device Trade Name:	Thora-3Di, Model T-01
Device Common Name:	Breathing Frequency Monitor
Device Classification:	21 CFR 868.2375, Breathing Frequency Monitor Product Code BZQ
Predicate Device:	K090273, Kai Spot KMS200, Kai Medical
Predicate Device Classification:	21 CFR 868.2375, Breathing Frequency Monitor Product Code BZQ

Device Description:

The Thora-3Di uses Structured Light Plethysmography (SLP) to derive respiratory rate. With the Thora-3Di, a structured grid pattern of light is projected onto the thoraco-abdominal wall and two digital video cameras record changes in the grid pattern due to movement of the wall. A dedicated parallel processor executes real-time pattern recognition algorithms to identify the position of each part of the virtual grid in each camera. The system computes the 3-dimensional coordinates of the different markers to assess respiratory rate.

The Thora-3Di does not include any wireless transmission features, nor does it include a cloud or other remote functionality (no cybersecurity-related features).

Indications for Use:

The Thora-3Di is intended for a one-time measurement of respiratory rate as part of a vital signs assessment. The device is indicated for hospital or clinical use in adult

patients. The device is intended to be operated by clinicians and medically qualified personnel. It is available for sale only upon the order of a physician or licensed health care provider.

The Thora-3Di is not intended to monitor vital signs. This device is not an apnea monitor.

Overview of Substantial Equivalence:

Characteristics	**PneumaCare's Thora-3Di**	**Kai Non-Contact RR Spot Check K090273**
Product Code	BZQ	BZQ
Primary output	Displays respiratory rate (RR)	Displays respiratory rate (RR)
Intended use	The Thora-3Di is intended for a one-time measurement of respiratory rate as part of a vital signs assessment. The device is indicated for hospital or clinical use in adult patients. The device is intended to be operated by clinicians and medically qualified personnel. It is available for sale only upon the order of a physician or licensed health care provider. The Thora-3Di is not intended to monitor vital signs. This device is not an apnea monitor.	Intended for a one-time measurement of respiratory rate as part of a vital signs assessment. The device is indicated for hospital or clinical use in adult patients. The device is intended to be operated by clinicians and medically qualified personnel. It is available for sale only upon the order of a physician or licensed health care provider. The Kai Sensors Non-Contact Respiratory Rate Spot Check Model 100 is not intended to monitor vital signs. This device is not an apnea monitor.
Intended use environment	In hospital or clinical care settings	In hospital or clinical care settings
Duration of monitoring	Up to 5 minutes (acute measurement)	Spot check measurement
Technology	Non patient contacting, works from distance through clothing	Non patient contacting, works from distance through clothing
Measurement positions	Subject is seated	Subject can be sitting or lying down
Clinical validation	Validated against Capnography (Clinician Over-Scored Capnography)	Validated against Embletta, Welch Allyn Propaq
Parameters displayed	Respiratory rate	Respiratory rate

Characteristics	PneumaCare's Thora-3Di	Kai Non-Contact RR Spot Check K090273
Technology Platform	Visual technique using two cameras and a projector to look at chest and abdominal wall movement	Uses a low power radar to sense chest displacement.

Rationale for Substantial Equivalence:

The Thora-3Di indications for use is identical to the predicate Kai Spot. The Thora-3Di and the predicate Kai Spot devices are similar in design in that both devices assess respiratory rate as a spot measurement, i.e. neither device is a continuous long term monitor. Both devices are non-patient contacting and have a similar technological approach of looking at signals generated from chest wall displacement to assess respiratory rate. The Thora-3Di uses Structured Light Plethysmography (SLP), an optical technique while the Kai Spot uses Doppler Radar to assess respiratory rate.

Both devices' respiratory rate output were compared to reference or predicate devices in clinical studies, and met the prospectively defined acceptance criteria, demonstrating substantial equivalence to their respective comparator devices.

Relevant Standards:
The Thora-3Di has been tested and meets the requirements of the relevant sections of the following performance standards:

- IEC 60601-1 Standard: Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (2005)
- IEC 60601-1-2 Standard: Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance, Collateral Standard: Electromagnetic Compatibility (2007)
- IEC 62304: First edition 2006-05, medical device software - software life cycle processes.
- ISO 14971: Second edition 2007-03-01, medical devices - application of risk management to medical devices.

Software documentation and processes also complied with the following FDA guidance documents:

- Draft Guidance for Industry and FDA Staff: Content of Premarket Submissions for Software Contained in Medical Devices(May 2005)
- FDA General Principles of Software Validation: Final Guidance for Industry and Staff (January 2002)

- Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices (September 1999)

Summary of Performance Data:

The Thora-3Di has been tested on the bench to demonstrate accuracy of respiratory rate between 2-60 brpm, where test conditions simulated different subject anatomies such as large abdomen and chest size, and weak breathing. The bench test also verified that the software displayed applicable user alerts as intended when measurements were taken outside of the labeled setup instructions. Software bench testing verified all software system requirements.

The Thora-3Di has also been evaluated in a clinical trial against the reference standard of capnography for the respiratory range of 8-25 brpm. 35 adult subjects between the ages of 19 and 77 meeting the study inclusion criteria were enrolled. The primary endpoint analysis was to compare the output respiratory rate of Thora-3Di with that of the COSC (Clinician Overscored CO_2 derived from the reference capnograph device) measured over one randomly selected epoch of one minute for each subject.

The acceptance criterion was based on a mean squared difference (MSD) <0.81 $brpm^2$ between the two devices which would indicate limits of agreement of +/- 2 brpm.

Results: The MSD was estimated to be 0.136 $brpm^2$ which is significantly less than the null hypothesis value of 0.81 $brpm^2$ (p-value=0.0002). The 95% limits of agreement were (-0.72, 0.75 brpm) which are much narrower than the pre-defined limits of agreement of (-2, 2 brpm).

Conclusion:

The Thora-3Di has similar intended use and indications statements as the predicate device, for the measurement of respiratory rate. In the bench study, the Thora-3Di showed an accuracy of </= +/-1 brpm for different simulated anatomies and simulated weak breathing. In a pivotal clinical study, Thora-3Di was compared to the reference capnograph device, using COSC for the measurement of respiratory rate (RR) in healthy adults and adults with respiratory disease or impairment. The 95% CI was in between -0.72 to 0.75 breaths per minute, which is equivalent to the predicate device's published[1] 95% CI of +1.8 and -4.5 BPM. Therefore, the Thora-3Di is substantially equivalent to the predicate device.

[1] Droitcour et al, Non-Contact Respiratory Rate Measurement Validation for Hospitalized Patients, Conf Proc IEEE Eng Med Biol Soc. 2009; 2009: 4812–4815