December 19, 2019

Shenzhen Fiber Medical Technology Co. Ltd.
% Donna-Bea Tillman
Senior Consultant
Biologics Consulting Group
1555 King Street, Suite 300
Alexandria, Virginia 22314

Re: K190775
Trade/Device Name: The RHEA Vital Sign Vigilance System
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: BZQ, DRT
Dated: November 18, 2019
Received: November 18, 2019

Dear Donna-Bea Tillman:

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,

for Michael Ryan
Division 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)*
K190775

Device Name
RHEA Vital Sign Vigilance System

Indications for Use *(Describe)*
The RHEA Vital Sign Vigilance System is intended for continuous measurement of respiration rate and heart rate for adults (≤150kg), in an automatic contact-less manner, in hospital or clinic setting during sleep or resting condition.

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."

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the RHEA Vital Sign Vigilance System is provided below.

1. SUBMITTER

Applicant:	Shenzhen Fiber Medical Technology Co. Ltd. Room 501, Sun Mate Science and Technology Mansion 2009 Shahe West Road Shenzhen, China 518057 Tel: +86-86540386
Contact:	Luo Li Regulatory Affair Manager Shenzhen Fiber Medical Technology Co. Ltd +86 18576650186 li@darma.co
Submission Correspondent:	Donna-Bea Tillman, Ph. Senior Consultant Biologics Consulting Group, Inc. 1555 King Street, Suite 300 Alexandria, VA 22314 (410) 531-6542 dtillman@biologicsconsulting.com
Date Prepared:	December 18, 2019

2. DEVICE

Device Trade Name:	The RHEA Vital Sign Vigilance System (models: EL30, EL60, EL90)
Device Common Name:	Breathing frequency monitor, Heart rate monitor
Classification Name	21 CFR 868.2375 Breathing frequency monitor 21 CFR 870.2300 Heart rate monitor
Regulatory Class:	Class II
Product Code:	BZQ/DRT

3. PREDICATE DEVICE

Predicate Device: K131379 - EarlySense System 2.0

4. DEVICE DESCRIPTION

The RHEA Vital Sign Vigilance System is designed for continuous and contact-less measurement of a patient's heart rate and respiratory rate. The system can also notify the user when the patient exits the bed.

The RHEA Vital Sign Vigilance System is available in three models. The only difference between the models is the color of the bedside unit.

Table 1: RHEA Vital Sign Vigilance System Models

Models	**Colors**
The RHEA Vital Sign Vigilance System EL30	Silver
The RHEA Vital Sign Vigilance System EL60	White
The RHEA Vital Sign Vigilance System EL90	Blue

The system incorporates three main components:

- Bedside unit (also referred to "main unit")
- Sensor unit (including fiber cable) (also referred to as "optical fiber sensor")
- Data Export Software (referred to in internal project documentation as 'data export software', referred to as 'Fiber Data Management software' in the operator's manual). This software is not considered a medical device, as explained below.

The sensor detects movement vibrations from the patient's body and converts them into an optical signal. The bedside unit receives the optical signal from the sensor, calculates the heart rate and respiratory rate, displays the vital signs on the screen in real-time, and records and stores the patient data.

5. INTENDED USE/INDICATIONS FOR USE

The RHEA Vital Sign Vigilance System is intended for continuous measurement of respiration rate and heart rate for adults(≤150kg), in an automatic contact-less manner, in hospital or clinic setting during sleep or resting condition

6. TECHNOLOGICAL COMPARISON

Feature	**Subject device – RHEA Vital Sign Vigilance System**	**Predicate device – The EarlySense 2.0 System K131379**
Product Code	BZQ/DRT	BZQ/DRT/DQA
Regulation Number	21 CFR 868.2375/870.2300	21 CFR 868.2375/870.2300/870.2700
Classification Name	Breathing Frequency Monitor/Monitor, Cardiac (incl. Cardiotachometer and rate alarm) monitor	Breathing Frequency Monitor, Cardiac monitor (including Cardiotachometer and rate alarm), Oximeter
Components	Bedside unit Sensor unit	Bed Sensing Unit Beside Unit Optional OEM Oximetry Module
Energy Source and Input	AC Power **Input Voltage:** 100~240V AC (±10%); **Input Current:** 0.5A **Frequency:** 50Hz/60Hz **Output Current:** 1.5A Max	AC Power **Input Voltage:** 100~240V AC (±10%); **Input Current:** 0.5A **Frequency:** 50Hz/60Hz **Output Current:** 0.9A Max
Battery	Lithium ion rechargeable battery used to power the system if the system is not connected to mains power, such as during patient transfer or during power failures. **Battery Capacity:** 5000mAh **Rated Voltage:** 3.7V DC	Lithium polymer rechargeable battery used to power the system if the system is not connected to mains power, such as during patient transfer or during power failures. **Battery Capacity:** unknown **Rated Voltage:** unknown
Sensor Technology	Optical Fiber	Piezoelectric
Heart Rate:	Measure heart rate in real-time when patient lies down on the mattress. **Measurement Range:** 30-170 bpm **Accuracy:** ±3 bpm or ±3%, whichever is greater **Resolution:** 1 bpm **Baseline period:** Less than 20s from the time patient start to stay still completely.	Measure heart rate in real-time when patient lies down on the mattress. **Measurement Range:** 30-170bpm **Accuracy:** ±4% or ±5 bpm, whichever is greater **Resolution:** Unknown **Baseline period:** Unknown

Feature	**Subject device –** **RHEA Vital Sign Vigilance System**	**Predicate device –** **The EarlySense 2.0 System K131379**
Respiratory Rate:	Measure heart rate in real-time when patient lays down on the mattress. **Measurement Range:**0-45 rpm **Accuracy:** 7-45rpm ±2 rpm 0-6rpm None **Baseline period:** Less than 30s from the time patient start to stay still completely.	Measure heart rate in real-time when patient lays down on the mattress. **Measurement Range:** 6-45 rpm **Accuracy:** ±4% or ±1.5rpm, whichever is greater **Resolution:** Unknown
"Unexpected motion" notification	"Unexpected motion" is shown on the bedside unit display when the patient is talking, moving or turning. This information is used an indication that there may be interference with the current signal.	Not included
Motion Measurement	Not included	Measurement of the frequency of patient movement
"Measurement out of range" notification	Identifies when the heart rate or respiratory rate is out of the measurement range.	Not included
Bed Status	Identifies if the patient in in bed or out of bed, and for how long the patient has been in bed or out of bed.	Identifies if the patient in in bed or out of bed, and for how long the patient has been in bed or out of bed.
Data storage and export	Patient data can be recorded and exported.	Patient data can be recorded and exported
User Interface Display at Bedside	Yes	No
Displayed Information	Information displayed at bedside unit: Heart rate Respiratory rate Unexpected motion notification Measurement out of range notification Bed status	Information displayed at the beside unit: Heart Rate Respiratory Rate Bed Status Motion Measurement
Weight	The sensor unit: 565g±10g The bedside unit: 540g±10g	The sensor unit: 730g The bedside unit: 235g±10g
Dimensions	The sensor unit: 35 (H) ×241 (W) × 600 (L) The bedside unit: 30 (H) ×165 (W) × 261 (L)	The sensor unit: 6.45 (H) ×210 (W) × 300 (L) The bedside unit: 65.07 (H) ×62 (W) × 145.6 (L)
Defibrillation Proof	No	No

The subject device has the same intended use and similar indications for use, fundamental technology, performance, functionality, and operation principle as the predicate device. The differences do not raise new questions of safety and effectiveness.

7. PERFORMANCE DATA

Biocompatibility Testing

There are no direct or indirect patient-contacting components of the subject device. Therefore, patient contact information is not needed for this device.

Electrical safety and electromagnetic compatibility (EMC)

The RHEA Vital Sign Vigilance System was assessed for conformity with the relevant requirements of the following standards and found to comply:

- ANSI/AAMI ES 60601-1:2005/(R) 2012 and A1:2012, C1:2009/(R) 2012 and A2:2010/(R) 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2:2014 (Fourth Edition) Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: electromagnetic disturbances – Requirements and tests.
- IEC 62133:2012 (Second Edition) Secondary cell and batteries containing alkaline or other non-acid electrolytes

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.

Bench Testing

The following performance testing demonstrates that the device meets all performance requirements:

- Parameter Performance Testing:

  This testing assessed the impact of the following factors on device performance:

  - Ratio of heart rate amplitude to respiration rate amplitude
  - Patient position with respect to the sensor
  - Mattress thickness
  - Mattress materials

- Patient weight

The testing also assessed the accuracy of heart rate and respiration rate measurements and on/off bed notifications using a simulator.

The results of the testing demonstrate that the performance of the RHEA device should not be significantly affected by variations in these factors within expected limits and that the device performs in accordance with specifications.

- Denoising Performance Testing

This testing evaluated the resistance of the RHEA device to common sources of motion artifact and system noise when compared to the predicate Early Sense device. Twenty normal volunteers were asked lay quietly on a bed and either the RHEA device or the predicate Early Sense device was placed under the mattress. Subjects were asked to perform a range of activities such as raising their hand or coughing, and the impact of these activities on the output of the monitoring device was noted. The results demonstrated that the RHEA device was able to identify potential sources of motion artifact more frequently than the predicate device, and that the time required for the RHEA device to recover from motion artifacts was within specifications and comparable to the predicate device.

Animal Testing

Not applicable. Animal studies are not necessary to establish the substantial equivalence of this device.

Clinical Data

The accuracy of the RHEA Vital Sign Vigilance System when compared against the reference IntelliVue Patient Monitor was confirmed for both heart rate and respiration rate.

The RHEA Vital Sign Vigilance System did not degrade toward the extremes of the observed range of heart rates (51 to 115 bpm) or respiratory rates (9 to 32 br/min) and did not vary with the patient diagnosis/hospital location or body weight. The respiration rate accuracy (but not the heart rate accuracy) decreased when subjects were awake (20% higher RMSD) but remained below the performance standard specified in the study protocol and varied among sites (the least accurate site's respiratory rate RMSD was 50% higher than the most accurate). EarlySense's respiratory rate accuracy was also worse with awake subjects and varied among sites and was in all cases worse than RHEA's.

No device-related adverse events nor significant malfunctions related to the investigational or reference device were observed.

These data demonstrate that the performance of the subject RHEA Vital Sign Vigilance System is substantially equivalent to that of the predicate EarlySense System 2.0 in regards to both safety and effectiveness.

8. CONCLUSION

The subject device has the same intended use and similar indications for use, fundamental technology, performance, functionality, and operation principle as the predicate device. Based on the detailed comparison between the predicate devices and the subject devices, the performance testing and conformance with applicable standards, the RHEA Vital Sign Vigilance System can be found substantially equivalent to the predicate device.