December 18, 2024

Cadwell Industries, Inc.
Jason Ford
Regulatory Affairs Manager
909 North Kellogg St.
Kennewick, Washington 99336

Re: K242424
Trade/Device Name: Bluebird Single-Use Respiratory Effort Belt
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: MNR
Dated: November 15, 2024
Received: November 15, 2024

Dear Jason Ford:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Rachana Visaria -S

Rachana Visaria, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242424

Device Name
Bluebird Single-Use Respiratory Effort Belt

Indications for Use *(Describe)*
The Bluebird Single-Use Respiratory Effort Belt is intended to measure respiratory effort to assist in the diagnosis of sleep disorders or sleep related respiratory disorders. The respiratory effort belt signals are suitable for connection to sleep/polysomnography (PSG) systems. The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments, including the patient's home.
The Bluebird Single-Use Respiratory Effort Belt is intended for diagnostic purposes only on patients greater than 2 years of age and is not intended to be used as 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K242424 510(k) Summary

Submitter Information

Submitter Name:	Cadwell Industries, Inc. 909 N. Kellogg Street Kennewick, Washington 99336
Submitter Phone:	509-735-6481
Contact Person:	Jason Ford Regulatory Affairs Manager
Date Summary Prepared:	November 15, 2024

Subject Device

Trade Name:	Bluebird Single-Use Respiratory Effort Belt
Common Name:	Respiratory Effort Sensor
Classification Name:	21 CFR 868.2375, Ventilatory Effort Recorder, Breathing Frequency Monitor Class II
Product Code:	MNR

Predicate Device

510(k) Number:	K173793
Trade Name:	XactTrace® Single Use Respiratory Effort Belt System
Submitter Name:	Natus Neurology
Classification Name:	21 CFR 868.2375, Breathing Frequency Monitor
Product Code:	MNR

Reference Predicate Device

510(k) Number:	K151361
Trade Name:	Nox RIP Belts and Nox RIP Belt Cables
Submitter Name:	Nox Medical
Classification Name:	21 CFR 868.2375, Breathing Frequency Monitor
Product Code:	MNR

Device Description

The Bluebird Single-Use Respiratory Effort Belt (Bluebird) is used to measure chest and abdomen expansion and contraction during respiration. The sensor consists of a sinusoidal wire coil attached along the length of an elastic belt. The inductance of the sensor changes as the belt is stretched. The Bluebird is suitable for connection to the inputs of physiological recording equipment. The Bluebird measures inductance and generates an output signal proportional to the amount of stretch. The elastic belt is held in place by a quick release buckle with a cinch function and the belt is adjusted to fit snugly but comfortably. Electrical connection to the two ends of the embedded coil is through a 1.5mm female touch proof connection jack on each side of belt buckle. The materials are elastics and plastics used in the clothing industry, and fine gauge copper wire for the embedded coil.

Indications for Use

The Bluebird Single-Use Respiratory Effort Belt is intended to measure respiratory effort to assist in the diagnosis of sleep disorders or sleep related respiratory disorders. The respiratory effort belt signals are suitable for connection to sleep/polysomnography (PSG) systems. The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments, including the patient's home.

The Bluebird Single-Use Respiratory Effort Belt is intended for diagnostic purposes only on patients greater than 2 years of age and is not intended to be used as an apnea monitor.

Summary of Technological Characteristics and Comparison to the predicate device

The Bluebird employs the same technological characteristics as the predicate device. The following table provides a side-by-side comparison of the Indications for Use and technological characteristics of the subject and predicate devices.

Feature	XactTrace Single-Use Respiratory Effort Belt System (Predicate K173793)	Bluebird Single-Use Respiratory Effort Belt (Subject Device)	Equivalence Comments, Discussion
Indications for Use	The XactTrace® Single Use Respiratory Effort Belt System is intended to measure respiratory effort to assist in the diagnosis of sleep disorders or sleep related respiratory disorders. The respiratory effort signals measured are processed to provide electrical signals suitable for connection to the inputs of physiological recording equipment. The intended environments are hospitals, institutions, sleep centers, sleep clinics. The XactTrace Single Use Respiratory Effort Belt System is intended for diagnostics purposes only and is not intended to be used as an apnea monitor.	The Bluebird Single-Use Respiratory Effort Belt is intended to measure respiratory effort to assist in the diagnosis of sleep disorders or sleep related respiratory disorders. The respiratory effort belt signals are suitable for connection to sleep/polysomnography (PSG) systems. The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments, including the patient's home. The Bluebird Single-Use Respiratory Effort Belt is intended for diagnostic purposes only on patients greater than 2 years of age and is not intended to be used as an apnea monitor.	There are no significant differences in the indications for use between the subject and predicate device. The specific use for patients 2 years and older is the same as found in the reference device, K151361.
Population of use	Adult and pediatric	greater than 2 years of age	No significant differences, see above comment to reference predicate.
Environment of Use	Hospitals, institutions, sleep centers, sleep clinics or other test environments, including the patient´s home.	Hospitals, institutions, sleep centers, sleep clinics, or other test environments, including the patient´s home.	Equivalent

Single patient use	Yes	Yes	Equivalent
Duration of use	Duration of clinical uses, anticipated to be ≤ 12 hours.	Duration of clinical uses, anticipated to be ≤ 12 hours.	Equivalent
Fundamental technology	Respiratory Inductive Plethysmography (RIP)	Respiratory Inductive Plethysmography (RIP)	Equivalent
Compatible recording technology	Physiological recording equipment	Physiological recording equipment	Equivalent
Belt Length Variations	Pre-sized	Pre - sized	Equivalent
Patient applied location	Abdomen and Thorax	Abdomen and Thorax	Equivalent
Pre-Sized Belt Sizes (Circumference)	Pre-sized variations of large, medium, small and pediatric (inches). Large: 40 to 75 Medium: 30 to 55 Small: 16 to 35 Pediatric: 11 to 22	Pre-sized variations of large, medium, small and pediatric (inches). Large: 40 to 75 Medium: 30 to 55 Small: 16 to 35 Pediatric: 11 to 22	Equivalent
Patient contact	Not in direct contact with bare skin.	Not in direct contact with bare skin.	Equivalent
Belt connectors	Touchproof safety connection, complying with DIN 42 802 for Touchproof connection systems.	Touchproof safety connection, complying with DIN 42 802 for Touchproof connection systems.	Equivalent
Belt Material	Elastic Band with Wire	Elastic Band with Wire	Equivalent
Buckle Material	ABS	Polypropylene	Equivalent. Both materials are commonly used for plastic mold injection during the manufacturing process. The differences in material do not affect the safety or efficacy of the device.
Performance Testing	Dimensional requirements Buckle functionality Compatibility with a PSG recorder Equivalence of breathing effort signal output Operational temperature and	Dimensional requirements Buckle functionality Compatibility with a PSG recorder Equivalence of breathing effort signal output	The performance testing for the subject device are equivalent to the predicate within the characteristics of Dimensional requirements, Buckle functionality, Compatibility with a PSG recorder and equivalency of breathing signal output. Cleaning

	humidity Resistance EMC compliance Cleaning		is not required since the subject device is a single use device. EMC and operational testing is not required for the subject device and is mitigated by the PSG recording device requirements. Therefore, these differences do not affect the safety or efficacy of the subject device.

Performance Testing

Nonclinical tests were performed on the subject device in order to show the technological equivalency to the predicate device and to verify the compliance to design requirements. No special controls exist for this type of device. Device testing included dimensional requirements, continuity, belt buckle function, ability to connect the subject device to a standard PSG recording device, recorded respiratory effort signal quality, packaging testing and comparative performance testing to the predicate.

The comparative performance testing provided direct performance comparison to the actual recorded output signal of each device. Performance testing was performed for the Bluebird rip belt connected to a Cadwell recording device and simultaneously to an XactTrace belt, therefore both belts acting as passive devices, connected to the same Cadwell PSG recorder. The resulting waveforms are the same for both belts.

Conclusion

The passing results of the nonclinical tests and the technological and Indications for Use comparison demonstrate the Bluebird Single-Use Respiratory Effort Belt is substantially equivalent to the legally marketed predicate device.