March 1, 2019

Embla Systems
Sanjay Mehta
Director, Quality Assurance & Regulatory Affairs
1 Hines Road, Suite 202
Kanata, k2k 3C7 Ca

Re: K173793
Trade/Device Name: XactTrace Single Use Respiratory Effort Belt System
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: MNR
Dated: January 29, 2019
Received: January 30, 2019

Dear Sanjay Mehta:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 -S

for Tina Kiang, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173793

Device Name
The XactTrace® Single Use Respiratory Effort Belt System

Indications for Use *(Describe)*
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.

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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K173793 510(k) Summary

Submitter Information

Submitter's Name:	Embla Systems
Submitter's Address:	1 Hines Road, Suite 202 Kanata, ON, CA, K2K 3C7
Submitter's Phone:	(905) 287-5055
Contact Person:	Mr. Sanjay Mehta Director, Quality Assurance & Regulatory Affairs
Date Summary Prepared:	February 27, 2019

Subject Device

Trade Name:	XactTrace® Single Use Respiratory Effort Belt System
Common Name:	Respiratory Effort Sensor
Classification Name:	21 CFR 868.2375, Ventilatory Effort Recorder Class II
Product Code:	MNR

Predicate Device(s)

510(k) Number:	K043132 (Primary Predicate)	K923402
Trade Name:	Universal XactTrace	Crystal Trace Piezo Respiratory Effort Sensor
Submitter Name:	Medcare Flaga	Pro-Tech, Inc.
Classification Name:	21 CFR 868.2375, Breathing frequency monitor	21 CFR 868.2375 Breathing frequency monitor
Product Code:	MNR	BZQ

510(k) Number:	K042253
Trade Name:	SleepSense Sleep Sensors
Submitter Name:	SLP Ltd.
Classification Name:	21 CFR 868.2375, Breathing frequency monitor
Product Code:	MNR

Reference Device(s)

510(k) Number:	K024322	K041724
Trade Name:	Embla N7000	Compass M10 System
Submitter Name:	Medcare Flaga	Medcare Flaga
Classification Name:	21 CFR 868.2375, Breathing frequency monitor	21 CFR 868.2375, Breathing frequency monitor
Product Code:	MNR	MNR

Device Description

The XactTrace Single Use Respiratory Effort Belt System subject device applies Respiratory Inductive Plethysmography (RIP) Sensor Belts to support respiratory effort signals used in the diagnosis of sleep disorders or sleep related respiratory disorders. The XactTrace Single Use Respiratory Effort Belt System subject device supports a measure of changes in inductance as a result of changes in abdominal, thorax circumference.

There are two variations of the XactTrace® Single Use Respiratory Effort Belt System:
1. XactTrace® Single Use Cut-to-Fit Respiratory Effort Belt System, and
2. XactTrace® Single Use Pre-Sized Respiratory Effort Belt System.

The XactTrace Single Use Cut-to-Fit Respiratory Effort Belt variation consists of a single use disposable Sensor Belt and Locks (belt connectors) with a cable that connects to a recording device. The system supports conversion

of changes in inductance to a digital signal that provides both qualitative and quantitative information of respiratory effort. The Sensor Belt of the XactTrace Single Use Cut-To-Fit Belt variation is cut by the medical professional to appropriate lengths to fit patient abdomen, thorax circumference.

The XactTrace Single Use Pre-Sized Respiratory Effort Belt variation consists of a single use disposable Sensor Belt and Snap Sensors (Sensor Belt connectors) with a cable that connects to a recording device. The XactTrace Single Use Pre-Sized Respiratory Effort Belt variation supports conversion of Sensor Belt changes in inductance to a signal that provides both qualitative and quantitative information of respiratory effort. XactTrace Single Use Pre-Sized Respiratory Effort belts are available in four sizes: Pediatric, Small, Medium and Large.

An optional Inductive Interface Cable (RIP Processor) is available to interface with PSG systems that accept the 1.5mm female touchproof connectors, and do not have internal RIP Sensor Belt technology.

Both variations of XactTrace Respiratory Effort Belts are interfaced with either an optional external Inductive Interface Cable or a RIP technology compatible Embla PSG system amplifier. Compatible Embla amplifiers are identified by keyhole connectors for Sensor Belt input.

Statement of Intended 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.

Summary of Technological Characteristics and Comparison to Predicate and Reference Devices

The fundamental RIP technology of the XactTrace® Single Use Respiratory Effort Belt System is the same as the primary predicate Universal XactTrace.

The comparison to the primary predicate Universal XactTrace Belt to create the XactTrace® Single Use Respiration Belt System under review are summarized as:

1. Creation of two single use variations:
   a. XactTrace Single Use Pre-Sized Respiratory Effort Belt
      Equivalent to the predicate Universal XactTrace reusable belt sizes, the single use disposable belt is available in pediatric, small, medium, and large sizes.
   b. XactTrace Single Use Cut-to-Fit Respiratory Effort Belt
      A single use disposable belt the medical professional cuts to fit the patient size. The Cut-to-Fit RIP sensor belt with associated Locks (connectors) is the same as described in K024322 and K041724.
2. The XactTrace Single Use Respiration Belts under review are either interfaced with RIP technology compatible Embla PSG systems or an external Inductive Interface Cable, which is an internal battery powered signal interface. The primary predicate Universal XactTrace is powered by a battery for interface within the Sensor Belt connector.

The following table provides a side-by-side comparison of the XactTrace Single Use Respiration Effort Belt System under review to the predicate devices applied to support this pre-market notification.

Feature	**XactTrace Single Use Respiratory Effort Belt System (under review)**	**Universal XactTrace (Primary Predicate, K043132)**	**Crystal Trace Piezo Respiratory Effort Sensor (K923402)**	**SLP Ltd. RIP Sensor, RIP Processor (K042253)**	**Equivalence Comments, Discussion**
Indications for Use	The XactTrace® Single Use Respiratory Effort Belt System is	Universal XactTrace is intended to measure	The Crystal Trace Piezo Respiratory Effort Sensor is intended for use	SleepSense sleep sensors provide a qualitative measure of some	Identical to the primary predicate Universal XactTrace

Feature	XactTrace Single Use Respiratory Effort Belt System (under review)	Universal XactTrace (Primary Predicate, K043132)	Crystal Trace Piezo Respiratory Effort Sensor (K923402)	SLP Ltd. RIP Sensor, RIP Processor (K042253)	Equivalence Comments, Discussion
	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.	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, or other test environments. Universal XactTrace is intended for diagnostics purposes only and is not intended to be used as an apnea monitor.	during sleep disorder studies to detect respiratory effort for recording onto a physiological recorder.	physiological parameters for recording onto an FDA-cleared data acquisition system. Their target population: Children and adult patients who are screened during sleep disorder studies. Their environment of use is usually at a sleep laboratory or sometimes at the patient's home.	with the exception of product name change. Equivalent to the predicate Crystal Trace Piezo Respiratory Effort Sensor and SLP Ltd. RIP Sensor and RIP Processor. Note: The SLP Ltd 510(k) addresses various sleep sensors and interface cables, including a RIP Sensor and RIP Processor.
Population of use	Adult and pediatric	Adult and pediatric	Adult and pediatric	Children and adults	Same
Environment of Use	Hospitals, institutions, sleep centers, sleep clinics.	Hospitals, institutions, sleep centers, sleep clinics, or other test environments.	Hospitals, institutions, sleep centers, sleep clinics, or other test environments.	Hospitals, institutions, sleep centers, sleep clinics, or other test environments.	Same
Single patient use	Yes	No, reusable	No, reusable	No, reusable	The XactTrace® Single Use Respiratory Effort Belt System, sensor belts under review is single patient use, disposable
Duration of use	Duration of clinical uses,	Duration of clinical uses,	Duration of clinical uses,	Duration of clinical uses,	Same

Feature	XactTrace Single Use Respiratory Effort Belt System (under review)	Universal XactTrace (Primary Predicate, K043132)	Crystal Trace Piezo Respiratory Effort Sensor (K923402)	SLP Ltd. RIP Sensor, RIP Processor (K042253)	Equivalence Comments, Discussion
	anticipated to be ≤ 12 hours.	anticipated to be ≤ 12 hours.	anticipated to be ≤ 12 hours.	anticipated to be ≤ 12 hours.	
Fundamental technology	Respiratory Inductive Plethysmography (RIP)	RIP	Piezo	RIP	Both RIP and Piezo technologies apply a change in circumference of a flexible Sensor Belt to provide a low level signal that is related to the change in circumference.
Variations	Cut-to-Fit Pre-sized	Pre-sized	Pre-sized	Pre-sized	Equivalent Pre-sized variations. The cut-to-fit variation was included in the Reference device 510(k) review.
Universal Rip variations (Use with non-Embla System)	Yes (two) Abdomen and Thorax	Yes (two) Abdomen and Thorax	Not applicable	Yes (two) Abdomen and Thorax	Same
Patient applied location	Abdomen and Thorax	Abdomen and Thorax	Abdomen and Thorax	Abdomen and Thorax	Same
User Adjustable Sensor Belt Lengths	Yes	Yes	Yes	Yes	Same
Pre-Sized Sensor Belt (Circumference)	XactTrace Single Use Respiratory Effort Belt System: 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	XactTrace Reusable Embla RIP Belts: Pre-size variations of large, medium, small and pediatric (inches). Large: 47 to 66 Medium: 33 to 56 Small: 22 to 41 Pediatric: 19 to 28	Yes Adult Size: 28 to 80 inches Pediatric (Ped) Size: 10.5 to 34 inches	Disposable: 120 cm and 150 cm	Both the primary predicate Universal XactTrace and XactTrace Single Use Respiratory Effort Belt System under review may be purchased in Pre-Sized belt lengths. The primary predicate Universal XactTrace 510(k) is applied to adult and pediatric patient populations, the same as the device under review. Variations are medical professional adjustable with regard to Sensor Belt length.
Patient contact	Not in direct contact with bare skin.	Not in direct contact with bare skin.	Yes	Unknown	Same as the primary predicate Universal XactTrace.

Feature	XactTrace Single Use Respiratory Effort Belt System (under review)	Universal XactTrace (Primary Predicate, K043132)	Crystal Trace Piezo Respiratory Effort Sensor (K923402)	SLP Ltd. RIP Sensor, RIP Processor (K042253)	Equivalence Comments, Discussion
Belt connectors and cables to recorder	Touchproof safety connection, complying with the 21 CFR 898 Performance Standard for Electrode Lead Wires and Patient Cables.	Touchproof safety connection, complying with the 21 CFR 898 Performance Standard for Electrode Lead Wires and Patient Cables.	Recessed female safety connection.	Recessed female safety connection, complying with the 21 CFR 898 Performance Standard for Electrode Lead Wires and Patient Cables.	Same.
Sensor Belt Material	Warp: Texturized polyester raw white Weft: Texturized polyester raw white Elasthane: Dorlastan Filament Type	Warped: Texturized polyester colored; Weft: Cotton; Elastic: Dorlastan Filament Type	Unknown	Unknown	The Sensor Belt material does not contact the patient.
Power source	XactTrace Single Use Respiratory Effort Belt System, Single Use Cut-to-Fit and Pre-Sized Universal RIP Belts: Interface with optional Inductive Interface Cable (RIP processor) (Non-replaceable 3 volt battery) XactTrace Single Use Respiratory Effort Belt System, Single Use Cut-to-Fit and Pre-Sized variations: Interface with Embla PSG system	XactTrace Reusable Universal RIP Belts: Non-replaceable 3 volt battery in connector (Snap Sensor) XactTrace Reusable Embla RIP Belts: Powered by Embla PSG system	None The piezo sensor belt self generates a small voltage in response to circumference change.	Non-replaceable 3 volt battery in RIP Processor	Same. The RIP technology power source is either a non-replaceable 3 volt battery or the Embla PSG system.
Maximum signal amplitude (peak to peak)	10 mV (Inductive Interface Cable (RIP Processor))	11.2 mV	Unknown	10 mV	The medical professional's recording equipment accommodates signal amplitudes with amplifier settings.

As noted, the differences do not affect substantial equivalence of safety and effectiveness.

- The Sensor Belt component is modified to support single patient use, disposable variations. The change to a single use disposable Sensor Belt does not raise new questions of safety or effectiveness.
- Cut-to-Fit and Pre-Sized variations of the XactTrace Single Use Respiratory Effort Belt System are available. The user can cut the Sensor Belt length in the Cut-to-Fit variation. The Pre-Sized XactTrace variations are

similar lengths as the primary predicate Universal XactTrace lengths. The selection and use of Sensor Belt length are at the discretion of the medical professional.

- The XactTrace Single Use Respiratory Effort Belt System connectors to the Sensor Belt do not contain any battery or signal conditioning electronics. The battery and signal conditioning is performed in an external, commercially available Inductive Interface Cable or a RIP technology compatible amplifier.

Modifications were performed in compliance with the Embla Systems design control process.

Performance Testing

To establish the technical equivalency of the XactTrace Single Use Respiratory Effort Belt System, non-clinical, bench evaluations were conducted to confirm compliance with performance requirements, summarized in the following table.

Requirement	Method	Result
Dimensional requirements	Measurement of components.	Pass
Lock and Snap Sensor compatibility	Components connect properly and perform as intended.	Pass
Compatibility with Inductive Interface Cable and RIP technology compatible Embla PSG recording system input connections, key connector inputs	Interface with Inductive Interface Cables and Embla PSG recording system input connections, key connectors, recoding.	Pass
Resistance of XactTrace Single Use Cut-to-Fit Effort Belt, variation of XactTrace Single Use Respiratory Effort Belt System	Cut belts to size, confirm resistance measurement.	Pass
Resistance of XactTrace Single Use Pre-Sized Effort Belt, variation of XactTrace Single Use Respiratory Effort Belt System	Confirm resistance measurement.	Pass
Cleaning of reusable Snap Sensor and Locks	Recommended cleaning method does not cause damage.	Pass
Operational temperature and humidity range	No damage with operational temperature and humidity.	Pass
Equivalence of breathing effort signal output	Compare breathing effort signal output for the XactTrace Single Use Respiratory Effort Belt System technology under review to primary predicate Universal XactTrace for both Embla amplifier and Inductive Interface Cable.	Pass
Equivalence of breathing effort signal output for same displacement of both XactTrace Single Use Sized Effort Belt, variations.	For the same displacement of Sensor Belt, the output from the XactTrace Single Use Cut-to-Fit Effort Belt is equivalent to the output from the XactTrace Single Use Pre-Sized Effort Belt.	Pass
EMC compliance with Inductive Interface Cables.	Confirm compliance with IEC 60601-1-2, 4th edition.	Pass

Conclusion

The performance of the XactTrace Single Use Respiratory Effort Belt System is confirmed. All design verification and validation results meet requirements. No new questions of safety or effectiveness are raised by the XactTrace Single Use Respiratory Belt System. The Embla Systems XactTrace Single Use Respiratory Belt System is equivalent to the predicate devices.