September 27, 2019

Embla Systems (Embla)
Sanjay Mehta
Director, Quality Assurance & Regulatory Affairs
1 Hines Road, Suite 202
Kanata, ON, CA K2K 3C7

Re: K180001
Trade/Device Name: Embla BreathSensors
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing frequency monitor
Regulatory Class: Class II
Product Code: MNR
Dated: August 26, 2019
Received: August 29, 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/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
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)*
K180001

Device Name
Embla BreathSensors

Indications for Use *(Describe)*
The Embla BreathSensor provides a qualitative air flow signal by oral and/or nasal temperature sensitive resistive components for recording onto a recording system in support of airflow analysis and sleep studies.

The Embla BreathSensor does not provide any diagnostic conclusion about the patient's condition to the user.

The Embla BreathSensor user is a qualified medical practitioner in a hospital environment only who will exercise their professional judgment in using this information.

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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K180001 510(k) Summary

510(k) Summary
This summary is provided to support the 510(k) pre-market notification for the Embla BreathSensors.

Company Name:	Embla Systems (Embla) 1 Hines Road, Suite 202 Kanata, ON, CA, K2K 3C7
Company Contact:	Mr. Sanjay Mehta Director, Quality Assurance & Regulatory Affairs Phone: (905) 287-5055 Email: Sanjay.Mehta@natus.com
Date Summary Prepared:	September 27, 2019
Trade Name:	Embla BreathSensors
Common Name:	Thermistor for Air Flow
Classification Name:	Breathing Frequency Monitor 21 CFR 868.2375 Product Code: MNR Class II
Predicate Device:	K913749 EdenTrace Airflow 3171, Sleep Lab Airflow 3170 EdenTec Corporation (Primary predicate) K042253 SleepSense Sleep Disorder Sensors S.L.P. Ltd

Product Description
The Embla BreathSensors (Model 970 Series) are airflow thermistors used as an accessory to a polysomnogram (PSG) or sleep study recording system. The BreathSensor family is comprised of two different variations: Models 971 Adult and Model 974 Small Adult/Child.

The BreathSensors are for use with any standard PSG amplifier or recorder. An interface cable connects the BreathSensor to the polysomnography equipment.

Embla BreathSensors are designed to provide a qualitative measure of respirations (flow) from the mouth and/or nose. The user selects the appropriate size of BreathSensor based on their clinical judgment.

The nasal and/or oral temperature sensor elements are carbon ink placed on a substrate. The carbon ink is the temperature sensitive material. Silver ink interfaces with the carbon ink temperature sensing elements to provide a connection to the interface cable.

The Embla BreathSensors are non-sterile, single patient use, disposable devices.

Intended Use of the Device
The Embla BreathSensor provides a qualitative air flow signal by oral and/or nasal temperature sensitive resistive components for recording onto a recording system in support of airflow analysis and sleep studies. The Embla BreathSensor does not provide any diagnostic conclusion about the patient's condition to the user. The Embla BreathSensor user is a qualified medical practitioner in a hospital environment who will exercise their professional judgment in using this information.

Summary of Technological Characteristics

The BreathSensors are single patient use, disposable sensors applied to a patient below the nose, (above the mouth), to support a qualitative indication of airflow from the nostrils and/or mouth. The BreathSensors are a form of thermistor, indicating airflow by temperature change. The accessory interface cables connect between the BreathSensor and user equipment for display and recording by the user's equipment.

Table 1 provides a side-by-side comparison of the BreathSensors to the predicate device applied to support this pre-market notification.

Table 1: Substantial Equivalence Technical Characteristics

Feature	BreathSensors Under Review	EdenTrace Airflow 3171, Sleep Lab Airflow 3170 (Primary Predicate K913749)	S.L.P. Ltd SleepSense Sleep Disorder Sensors (Predicate K042253)	Equivalence Comments
Intended Use	Disposable temperature sensitive sensor to support recording airflow.	Disposable temperature sensitive sensor to support recording airflow.	Disposable temperature sensitive sensor to support recording airflow.	Same
Indications for Use	The Embla BreathSensor provides a qualitative air flow signal by oral and/or nasal temperature sensitive resistive components for recording onto a recording system in support of airflow analysis and sleep studies. The Embla BreathSensor does not provide any diagnostic conclusion about the patient's condition to the user. The Embla BreathSensor user is a qualified medical practitioner who will exercise their professional judgment in using this information. Rx only	The airflow signal is provided by oral and/ or nasal temperature sensitive components. Accessory single use airflow sensors are used to provide resistance changes as affected by temperature changes in airflow representing inhaled and exhaled air. Rx only	SleepSense sensors provide a qualitative measure of a patient's 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. Rx Only	Both the Embla BreathSensors under review and primary predicate Airflow Sensors provide oral and/or nasal temperature sensitive components. The population of use of the Embla BreathSensors under review and primary predicate EdenTec Airflow Sensors are similar. The variations of the primary predicate Airflow Sensors and Embla BreathSensors under review are identified by a Model variation name (Adult, Small Adult / Child). All three devices apply interface cables as applicable to condition the signal for medical professional user's recording equipment. All Rx Only The Embla BreathSensors under review provide additional detail with regard to the indications.
Contraindication	Contraindicated for use on patients who exhibit	None	None	The allergic reaction to tape adds clarification on

Table 1: Substantial Equivalence Technical Characteristics

Feature	BreathSensors Under Review	EdenTrace Airflow 3171, Sleep Lab Airflow 3170 (Primary Predicate K913749)	S.L.P. Ltd SleepSense Sleep Disorder Sensors (Predicate K042253)	Equivalence Comments
	allergic reactions to adhesive tape.			use.
Environment of Use	Hospitals	Hospitals, clinics and home.	Hospitals, clinics (sleep labs) and home.	The Embla Breath Sensors have a hospital environment of use.
Sensor variations	BreathSensor Adult, Small Adult / Child	Airflow Sensor Adult, Small Adult, Child, Infant, Preemie	Disposable Thermal Flow Sensor Adult, Child, Extra Small	Similar The medical professional selects the size of BreathSensor that best fits their patient with regard to placement of nasal and oral BreathSensor elements.
Temperature Sensing Elements	Breath Sensor Nasal and Oral: Adult, Small Adult / Child,	Airflow Sensor Nasal and Oral: Adult, Small Adult, Child, Infant Oral only: Preemie	Disposable Flow Sensor Nasal and Oral, Oral only options: Adult, Child, Extra Small	Similar The primary predicate variation names of Small Adult and Child are renamed to one variation.
BreathSensor: Single patient use, disposable	Yes	Yes	Yes	Same
Qualitative temperature output	Yes	Yes	Yes	Same The signal output from the BreathSensor is a qualitative signal based upon the difference in ambient and exhaled air. The medical professional will adjust signal amplitude on the recording equipment.
Duration of use	Duration of a sleep study, anticipated to be up to 12 hours	Duration of a sleep study	Duration of a sleep study	Same
Patient applied location	Between upper lip and nostrils	Between upper lip and nostrils	Between upper lip and nostrils	Same
Sensor materials	Carbon Ink Silver Ink Polyester Tape	Carbon Ink Silver Ink Polyester (Mylar) Tape	Unknown	Carbon ink is the temperature sensitive material. The conductive silver ink conducts the signal to the interface cable input connector. The carbon and silver ink are placed on a polyester substrate. The polyester substrate and ink are

Table 1: Substantial Equivalence Technical Characteristics

Feature	BreathSensors Under Review	EdenTrace Airflow 3171, Sleep Lab Airflow 3170 (Primary Predicate K913749)	S.L.P. Ltd SleepSense Sleep Disorder Sensors (Predicate K042253)	Equivalence Comments
				covered by tape.
Patient contact material	Micro-Pore, Micro-Foam Tape	Micro-Pore Tape	Unknown	Equivalent Final finished form BreathSensors have been evaluated for cytotoxicity, irritation and sensitization with passing results.
Sterility	Supplied non-sterile	Supplied non-sterile	Supplied non-sterile	Same
Accessory Interface cables	Yes Active	Yes Passive and active	Yes Passive and active	Similar Active interface cable variations are available. The interface cables connect to the medial professional's amplifier, recording equipment, supporting transfer of the BreathSensor thermistor signal to their equipment.
Accessory Interface cable: Active Cable	Yes Battery powered, filtering and conversion of sensor thermistor to thermocouple sensor signal.	Yes Battery Powered, filtering and conversion of sensor thermistor to thermocouple sensor signal.	Yes Battery Powered, filtering and conversion of sensor thermistor to thermocouple sensor signal.	Equivalent The active interface cables have sensor and user recording equipment compatible connectors and are battery powered (internal). The active interface cables are battery-powered by an internal non-user replaceable battery. The active interface cables provide filtering and conversion of the thermistor sensor signal to thermocouple sensor signal for presentation to the user's recording equipment
Accessory interface cable: Reusable	Yes	Yes	Yes	Same
Connection to user's equipment	Yes Accessory Interface Cable	Yes Accessory Interface Cable	Yes Accessory Interface Cable	Same
Interface cable variations	Active	Active and passive	Active and passive	Similar The active interface cables interface the BreathSensor

Table 1: Substantial Equivalence Technical Characteristics				
Feature	**BreathSensors Under Review**	**EdenTrace Airflow 3171, Sleep Lab Airflow 3170 (Primary Predicate K913749)**	**S.L.P. Ltd SleepSense Sleep Disorder Sensors (Predicate K042253)**	**Equivalence Comments**
				to recording equipment.

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

- A contraindication is added for patients who may have allergic reactions to adhesive tape.
- The BreathSensors are supported by available accessory interface cable(s).

Performance Tests to Demonstrate Substantial Equivalency

To establish the technical equivalency of the BreathSensors, evaluations were conducted to confirm compliance with performance requirements. Table 2 summarizes evaluations and results supporting substantial equivalence.

Table 2: Summary of Evaluations Supporting Substantial Equivalence		
Feature	**Evaluation Summary**	**Result**
Dimensions	Verification of dimensions.	Pass
Labels and Labeling	Verification of label and labeling content for variations.	Pass
Material	Verification of specified materials.	Pass
Biocompatibility of patient contact materials	Supported with final finished form cytotoxicity, sensitization and irritation evaluations.	Pass
Resistance	Verify BreathSensor base resistance.	Pass
Temperature Sensitivity	Verify minimum temperature sensitivity of resistance change per ºC.	Pass
Performance Testing	Comparison with predicate Disposable Flow Sensor, evaluation of qualitative airflow response with Interface Cable.	Pass
Electromagnetic compatibility	BreathSensor and Interface Cable compliance with IEC 60601-1-2:2014, 4th edition	Pass

Conclusion

The Embla BreathSensors meet performance requirements. The intended use and technology of the Embla BreathSensors are similiar to the predicate devices.