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.


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

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
Device Name
Embla BreathSensors

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 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Department of Health and Human Services
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Office of Chief Information Officer
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"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."
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>
<thead>
<tr>
<th>Feature</th>
<th>BreathSensors Under Review</th>
<th>EdenTrace Airflow 3171, Sleep Lab Airflow 3170 (Primary Predicate K913749)</th>
<th>S.L.P. Ltd SleepSense Sleep Disorder Sensors (Predicate K042253)</th>
<th>Equivalence Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended Use</td>
<td>Disposable temperature sensitive sensor to support recording airflow.</td>
<td>Disposable temperature sensitive sensor to support recording airflow.</td>
<td>Disposable temperature sensitive sensor to support recording airflow.</td>
<td>Same</td>
</tr>
<tr>
<td>Indications for Use</td>
<td>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 user is a qualified medical practitioner who will exercise their professional judgment in using this information.</td>
<td>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.</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>Contraindication</td>
<td>Contraindicated for use on patients who exhibit allergic reaction to tape adds clarification on</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Feature</td>
<td>BreathSensors Under Review</td>
<td>EdenTrace Airflow 3171, Sleep Lab Airflow 3170 (Primary Predicate K913749)</td>
<td>S.L.P. Ltd SleepSense Sleep Disorder Sensors (Predicate K042253)</td>
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</tr>
<tr>
<td>-------------------------------</td>
<td>-----------------------------</td>
<td>--------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------</td>
<td>----------------------</td>
</tr>
<tr>
<td>Environment of Use</td>
<td>Hospitals</td>
<td>Hospitals, clinics and home.</td>
<td>Hospitals, clinics (sleep labs) and home.</td>
<td>The Embla Breath Sensors have a hospital environment of use.</td>
</tr>
<tr>
<td>Qualitative temperature output</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>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.</td>
</tr>
<tr>
<td>Duration of use</td>
<td>Duration of a sleep study, anticipated to be up to 12 hours</td>
<td>Duration of a sleep study</td>
<td>Duration of a sleep study</td>
<td>Same</td>
</tr>
<tr>
<td>Patient applied location</td>
<td>Between upper lip and nostrils</td>
<td>Between upper lip and nostrils</td>
<td>Between upper lip and nostrils</td>
<td>Same</td>
</tr>
<tr>
<td>Sensor materials</td>
<td>Carbon Ink, Silver Ink, Polyester Tape</td>
<td>Carbon Ink, Silver Ink, Polyester (Mylar) Tape</td>
<td>Unknown</td>
<td>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</td>
</tr>
</tbody>
</table>
### Table 1: Substantial Equivalence Technical Characteristics

<table>
<thead>
<tr>
<th>Feature</th>
<th>BreathSensors Under Review</th>
<th>EdenTrace Airflow 3171, Sleep Lab Airflow 3170 (Primary Predicate K913749)</th>
<th>S.L.P. Ltd SleepSense Sleep Disorder Sensors (Predicate K042253)</th>
<th>Equivalence Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient contact material</td>
<td>Micro-Pore, Micro-Foam Tape</td>
<td>Micro-Pore Tape</td>
<td>Unknown</td>
<td>Equivalent Final finished form BreathSensors have been evaluated for cytotoxicity, irritation and sensitization with passing results.</td>
</tr>
<tr>
<td>Sterility</td>
<td>Supplied non-sterile</td>
<td>Supplied non-sterile</td>
<td>Supplied non-sterile</td>
<td>Same</td>
</tr>
<tr>
<td>Accessory Interface cables</td>
<td>Yes</td>
<td>Yes Passive and active</td>
<td>Yes Passive and active</td>
<td></td>
</tr>
<tr>
<td>Accessory Interface cable: Active</td>
<td>Yes Battery powered, filtering and conversion of sensor thermistor to thermocouple sensor signal.</td>
<td>Yes Battery Powered, filtering and conversion of sensor thermistor to thermocouple sensor signal.</td>
<td>Yes Battery Powered, filtering and conversion of sensor thermistor to thermocouple sensor signal.</td>
<td>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</td>
</tr>
<tr>
<td>Accessory Interface cable: Reusable</td>
<td>Yes</td>
<td>Yes Active</td>
<td>Yes Active</td>
<td>Same</td>
</tr>
<tr>
<td>Connection to user’s equipment</td>
<td>Yes Accessory Interface Cable</td>
<td>Yes Accessory Interface Cable</td>
<td>Yes Accessory Interface Cable</td>
<td></td>
</tr>
<tr>
<td>Interface cable variations</td>
<td>Active</td>
<td>Active and passive</td>
<td>Active and passive</td>
<td>Similar The active interface cables interface the BreathSensor</td>
</tr>
</tbody>
</table>

- **Patient contact material**
  - BreathSensors: Micro-Pore, Micro-Foam Tape
  - EdenTrace Airflow 3170: Micro-Pore Tape
  - S.L.P. Ltd SleepSense: Unknown

- **Sterility**
  - BreathSensors: Supplied non-sterile
  - EdenTrace Airflow 3170: Supplied non-sterile
  - S.L.P. Ltd SleepSense: Supplied non-sterile

- **Accessory Interface cables**
  - BreathSensors: Yes
    - EdenTrace Airflow 3170: Yes Passive and active
    - S.L.P. Ltd SleepSense: Yes Passive and active

- **Accessory Interface cable: Active**
  - BreathSensors: Yes Battery powered, filtering and conversion of sensor thermistor to thermocouple sensor signal.
  - EdenTrace Airflow 3170: Yes Battery Powered, filtering and conversion of sensor thermistor to thermocouple sensor signal.
  - S.L.P. Ltd SleepSense: Yes Battery Powered, filtering and conversion of sensor thermistor to thermocouple sensor signal.

- **Accessory Interface cable: Reusable**
  - BreathSensors: Yes
  - EdenTrace Airflow 3170: Yes
  - S.L.P. Ltd SleepSense: Yes

- **Connection to user’s equipment**
  - BreathSensors: Yes Accessory Interface Cable
  - EdenTrace Airflow 3170: Yes Accessory Interface Cable
  - S.L.P. Ltd SleepSense: Yes Accessory Interface Cable

- **Interface cable variations**
  - BreathSensors: Active
  - EdenTrace Airflow 3170: Active and passive
  - S.L.P. Ltd SleepSense: Active and passive

- **Equivalence Comments**
  - BreathSensors: Covered by tape.
  - EdenTrace Airflow 3170: Similar
  - S.L.P. Ltd SleepSense: Equivalent
Table 1: Substantial Equivalence Technical Characteristics

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</tr>
</thead>
<tbody>
<tr>
<td>Dimensions</td>
<td></td>
<td></td>
<td></td>
<td>to recording equipment.</td>
</tr>
<tr>
<td>Labels and Labeling</td>
<td>Verification of label and labeling content for variations.</td>
<td></td>
<td></td>
<td>Pass</td>
</tr>
<tr>
<td>Material</td>
<td>Verification of specified materials.</td>
<td></td>
<td></td>
<td>Pass</td>
</tr>
<tr>
<td>Biocompatibility of patient contact materials</td>
<td>Supported with final finished form cytotoxicity, sensitization and irritation evaluations.</td>
<td></td>
<td></td>
<td>Pass</td>
</tr>
<tr>
<td>Resistance</td>
<td>Verify BreathSensor base resistance.</td>
<td></td>
<td></td>
<td>Pass</td>
</tr>
<tr>
<td>Temperature Sensitivity</td>
<td>Verify minimum temperature sensitivity of resistance change per °C.</td>
<td></td>
<td></td>
<td>Pass</td>
</tr>
<tr>
<td>Performance Testing</td>
<td>Comparison with predicate Disposable Flow Sensor, evaluation of qualitative airflow response with Interface Cable.</td>
<td></td>
<td></td>
<td>Pass</td>
</tr>
</tbody>
</table>

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**

<table>
<thead>
<tr>
<th>Feature</th>
<th>Evaluation Summary</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimensions</td>
<td>Verification of dimensions.</td>
<td>Pass</td>
</tr>
<tr>
<td>Labels and Labeling</td>
<td>Verification of label and labeling content for variations.</td>
<td>Pass</td>
</tr>
<tr>
<td>Material</td>
<td>Verification of specified materials.</td>
<td>Pass</td>
</tr>
<tr>
<td>Biocompatibility</td>
<td>Supported with final finished form cytotoxicity, sensitization and irritation evaluations.</td>
<td>Pass</td>
</tr>
<tr>
<td>Resistance</td>
<td>Verify BreathSensor base resistance.</td>
<td>Pass</td>
</tr>
<tr>
<td>Temperature Sensitivity</td>
<td>Verify minimum temperature sensitivity of resistance change per °C.</td>
<td>Pass</td>
</tr>
<tr>
<td>Performance Testing</td>
<td>Comparison with predicate Disposable Flow Sensor, evaluation of qualitative airflow response with Interface Cable.</td>
<td>Pass</td>
</tr>
</tbody>
</table>

**Conclusion**

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