October 2, 2025

Exemplar Medical, LLC
Christian Moore
Managing Director
4521 Wornall Road Ste 106
Kansas City, Missouri 64111

Re: K250860
Trade/Device Name: BreatheBand® (Model 1000)
Regulation Number: 21 CFR 868.5665
Regulation Name: Powered percussor
Regulatory Class: Class II
Product Code: BYI
Dated: January 20, 2025
Received: March 21, 2025

Dear Christian Moore:

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,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
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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.

Submission Number *(if known)*

K250860

Device Name

BreatheBand® (Model 1000)

Indications for Use *(Describe)*

The BreatheBand® device is intended to deliver high-frequency chest wall oscillation (HFCWO) therapy to promote airway clearance and aid in general bronchial drainage when external chest manipulation or manipulation of the thorax is the physician's treatment of choice to enhance mucus transport.

It is indicated for adult patients (22 years of age and older) experiencing difficulty with secretion clearance.

The BreatheBand® device is intended for use in the home-care environment.

The BreatheBand® device is non-invasive, reusable, and intended for single-patient use.

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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Date of Summary:	March 14, 2025
Submitter:	Exemplar Medical, LLC 4521 Wornall Road Ste 106 Kansas City, MO 64111
Application Correspondent:	Christian Moore Exemplar Medical, LLC 4521 Wornall Road Ste 106 Kansas City, MO 64111 913.948.6100 (telephone)702.569.4584 (mobile) christian@exemplar-medical.com
Manufacturer's Information	Exemplar Medical, LLC 4521 Wornall Road Ste 106 Kansas City, MO 64111 913.948.6100 (telephone)

Device Identification

Type of 510(K):	Traditional
Trade or Proprietary Name:	BreatheBand®, Model 1000
Common or Usual Name:	Powered Percussor
Product Code:	BYI
Classification Name:	Standard Product Nomenclature: Percussor, Powered-Electric
Class of Device:	Class II
Panel:	Anesthesiology
Prior Related Submission:	None

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Regulation Number:	21 CFR 868.5665
Performance Standards:	Special controls or performance standards are not currently required for Percussor, Powered-devices under section 513 of the Act.

Identification of the Predicate Device and Reference Device:

Predicate Device:	IBC AffloVest (K122480)
Reference Device:	Hill-Rom Monarch Airway Clearance System (K163378)

Device Description:

The BreatheBand® Model 1000 (BreatheBand®) consists of the following major components:

2 Bands, each Band has 4 actuator 'Pods,' a control box, and fasteners.

1 Remote, which is a touchscreen device for controlling the Bands.

3 Charging Power Supplies for charging both Bands and the Remote simultaneously.

1 Carrying Case, which can house and protect the system when not in use.

1 Instructions For Use (IFU) document.

The Bands are worn across the thorax in an "X" configuration as demonstrated in the IFU. The Remote communicates with the Bands to control the actuators' settings, such as frequency, intensity, and duration of treatment, to implement the prescribed treatment as specified by a physician. In addition, error messages are displayed on the Remote screen when indicated. The treatment status, such as settings and length of the treatment remaining, as well as the system status (battery levels), are displayed on the Remote screen.

The Bands are adjustable in terms of overall length (to fit larger or smaller torso sizes) . Once adjustments are made to the fit, the user can remove and replace the Bands without re-adjusting.

Charging the Bands and Remote batteries is accomplished between therapy sessions, and the system will not provide therapy while connected to a charger. The battery capacity is sufficient for three typical therapy sessions on one full battery charge.

Indications for Use:

The BreatheBand® device is intended to deliver high-frequency chest wall oscillation (HFCWO) therapy to promote airway clearance and aid in general bronchial drainage when external chest manipulation or manipulation of the thorax is the physician's treatment of choice to enhance mucus transport.

It is indicated for adult patients (22 years of age and older) experiencing difficulty with secretion clearance.

The BreatheBand® device is intended for use in the home-care environment.

The BreatheBand® device is non-invasive, reusable, and intended for single-patient use.

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Intended Patient Population:

The BreatheBand® system is intended for adult patients in the home care environment and are expected to operate the device to self-administer therapy treatment. In addition, users are expected to handle the setup, cleaning, and storage of the device.

Users of the system should be able to read and understand Western Arabic numerals and the native language used in the manual. We recommend that the users of the device have an 8th-grade reading level or comparable.

Table 5-1 – Substantial Equivalence Comparison of the Subject Device to the Predicate and Reference

Feature	Subject Device	Predicate Device	Reference Device	Comments
	BreatheBand® System	**IBC AffloVest**	**Hill-Rom Monarch Airway Clearance System**	
Pre-Market Notification Number	**This 510(k) submission**	**K122480**	**K163378**	
Classification	CFR 21 part 868 Sec 868.5665 Powered-electric Percussor	CFR 21 part 868 Sec 868.5665 Powered-electric Percussor	CFR 21 part 868 Sec 868.5665 Powered-electric Percussor	Same
Substantial Equivalence Technological Characteristics				
Indications for Use	The BreatheBand® device is intended to deliver high-frequency chest wall oscillation (HFCWO) therapy to promote airway clearance and aid in general bronchial drainage when external chest manipulation or manipulation of the thorax is the physician's treatment of choice to enhance mucus transport.	The International Biophysics Corporation AffloVest is intended for promoting airway clearance and improvement of bronchial drainage by enhancing mobilization of bronchial secretions where external manipulation of the thorax is the physician's choice of treatment.	The Monarch™ product is intended to provide Airway Clearance Therapy and promote bronchial drainage where external manipulation of the thorax is the physician's choice of treatment. It is indicated for patients having difficulty with secretion clearance, or the presence of	Substantially Equivalent

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<table>
<tr><th>Feature</th><th colspan="2">Subject Device</th><th colspan="2">Predicate Device</th><th>Reference Device</th><th>Comments</th></tr>
<tr><td></td><td colspan="2">BreatheBand® System</td><td colspan="2">IBC AffloVest</td><td>Hill-Rom Monarch Airway Clearance System</td><td></td></tr>
<tr><td></td><td colspan="2">It is indicated for adult patients (22 years of age and older) experiencing difficulty with secretion clearance.
The BreatheBand® device is intended for use in the home-care environment.
The BreatheBand® device is non-invasive, reusable, and intended for single patient use.</td><td colspan="2"></td><td>atelectasis caused by mucus plugging.

The Monarch™ Airway Clearance System is intended to be used in the Home Care environment by patients, 15 years and older.</td><td></td></tr>
<tr><td>Patient Population</td><td colspan="2">Adult 22 years and older</td><td colspan="2">Not specified</td><td>15 years and older</td><td>Subset of predicate</td></tr>
<tr><td>Environment of Use: Homecare</td><td colspan="2">Yes</td><td colspan="2">Yes</td><td>Yes</td><td>Same</td></tr>
<tr><td>External Manipulation of the Chest</td><td colspan="2">Yes</td><td colspan="2">Yes</td><td>Yes</td><td>Same</td></tr>
<tr><td rowspan="10">Sizing System</td><td>Code</td><td>Chest girth (men/women) (cm)</td><td>Code</td><td>Chest girth (men/women) (cm)</td><td rowspan="10">One size which supports chest girth of 55.9 cm to 127 cm with hook-loop adjustment</td><td rowspan="10"><u>Substantially Equivalent</u>
BreatheBand size offerings are a subset of the predicate (i.e., BreatheBand sizes fall within the minimum and maximum chest girths accommodated by our predicate). This does not raise any new concerns of safety or effectiveness. BreatheBand sizing closely aligns with the guidelines presented in EN 13402-3.</td></tr>
<tr><td>XXS</td><td>66-76</td><td>XXS</td><td>46-58</td></tr>
<tr><td>XS</td><td>76-86</td><td>XS</td><td>58-74</td></tr>
<tr><td>S</td><td>86-96</td><td>S</td><td>74-89</td></tr>
<tr><td>M</td><td>96-106</td><td>M</td><td>89-104</td></tr>
<tr><td>L</td><td>106-116</td><td>L</td><td>104-122</td></tr>
<tr><td>XL</td><td>116-126</td><td>XL</td><td>122-140</td></tr>
<tr><td>XXL</td><td>126-136</td><td>XXL</td><td>140-165</td></tr>
<tr><td>N/A</td><td>N/A</td><td>XXXL</td><td>165-190.5</td></tr>
<tr><td colspan="7">Substantial Equivalence System Characteristics</td></tr>
<tr><td>Wearable with Zones of Direct Oscillations</td><td colspan="2">8 Zones</td><td colspan="2">8 Zones</td><td>8 zones</td><td>Same</td></tr>
<tr><td>Principle of Operation / Technology (Patient Interface)</td><td colspan="2">Two bands. Each band has installed: four electro-mechanical therapy pods and one control box.
Adjustable center buckle and strap accessories for snug and evenly distributed fit.
Battery powered.
Hand-held remote control for adjusting frequency, intensity and duration of treatments.</td><td colspan="2">Vest with installed oscillating vibratory motors organized into four zones.
Buckles and straps on the front and shoulders for snug and evenly-distributed fit.
Battery and AC/DC powered.
Remote wired into the vest to adjust the intensity of the oscillation.</td><td>Vest with installed oscillating electromechanical actuators organized into eight zones which include permanent magnets as part of the actuators.
Zipper, hook and loops on the front and shoulders for snug and evenly-distributed fit.</td><td>Substantially Equivalent</td></tr>
</table>

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Feature	Subject Device	Predicate Device	Reference Device	Comments
	BreatheBand® System	**IBC AffloVest**	**Hill-Rom Monarch Airway Clearance System**	
	The Remote communicates via Bluetooth. Motor pods deliver chest wall oscillation that mimics cup-hand manual therapy.	Vibration and oscillation of the user's chest wall is generated through integrated motor modules, installed into various parts of the vest.	Battery and AC/DC powered. Remote wired into the Garment to adjust the intensity of the oscillation. Bluetooth with App for optional control via Smartphone Wi-Fi for device usage data transmission.	
Technology of Oscillations	Electric Motors (Linear)	Electric Motors (Vibration)	Electric Motor (Linear)	Substantially Equivalent
Oscillation Frequency	4 Hz to 20 Hz	Percussion (Pulse) at 4 Hz Vibration frequency 5Hz to 20Hz	5 Hz to 20 Hz	Similar
Oscillation Amplitude	Oscillation Amplitude is correlated to Force. See Therapy Force entries below in this table.	With vibration motors, the amplitude of the oscillation does not change (unbalance load spinning on the shaft). Force is created by the unbalanced load and therapeutic forces listed below in this table.	Oscillation Amplitude is correlated to Force. See Therapy Force entries below in this table.	Substantially Equivalent
Power Source	110 VAC Charging Power Supply 3.65 V Battery	110 VAC Charging Power Supply 14.8V Battery	100 -240 VAC 24 V Battery	Substantially Equivalent Batteries have different working voltages, but this does not raise any new concerns of safety or effectiveness.
Battery Duration	Three 20-minute therapy sessions per charge (worst case settings)	Not available	Not available	Predicate and reference device do not specify battery duration in published documents.
Treatment Parameters	Manual Settings Pre-set and Saved Therapy Programs	Manual Settings Pre-set Therapy Programs	Manual Programmable	Substantially Equivalent
Treatment Modes	Pulse Vibration Cough Pause	Percussion (Pulse) Vibration Drainage	Pulse/Vibration Cough Pause	Similar
Therapy Time	User specified from 1 to 30 minutes	User specified from 5 to 15 minutes	User selectable from 1 to 60 minutes	Substantially Equivalent
Number and Types of Alarms	No audible alarms Led on Bands to indicate error states, battery	No audible alarms.	No audible alarms. On-screen indication of errors/warnings,	Substantially Equivalent No device produces audible alarms.

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Feature	Subject Device	Predicate Device	Reference Device	Comments
	BreatheBand® System	**IBC AffloVest**	**Hill-Rom Monarch Airway Clearance System**	
	status, and charge status. On-screen display for warning/error messages, battery status, and charge status.	On-screen indication of error/warnings, battery status.	battery status, and charge status.	Warnings, errors, and status are available on-screen for each device.
Force Magnitude Settings	User selectable from 1 to 10	Low Medium High	User selectable from 1 to 10	Substantially Equivalent
Therapy Force at Highest Setting	13.13 N	9.5 N (Published) 9.92N (Measured)	33.14 N	Substantially Equivalent
Therapy Force at Lowest Setting	3.3 N	4.9 N	7.2 N	Substantially Equivalent
Percussion and Drainage	Pulse mode 4Hz Drainage mode can be achieved by scheduling motor intensity/frequency changes in the therapy profile.	Percussion Mode - cycling motor power on/off at about 4Hz to simulate percussion. Drainage- Cycling motors at low intensity to promote drainage	Pulse mode 4Hz Drainage mode can be achieved by scheduling motor intensity/frequency changes in the therapy profile.	Substantially Equivalent Subject and reference devices have the capability to scheduling and saving a therapy profile to provide an equivalent mode to the predicate's drainage mode.
Acoustic Energy	51 dBA @ 1m	48 dBA @1 m	65 dBA	Substantially Equivalent 55dBA was measured at user ear location for BB as per 60601 test setup. This value is measured at 1m from the device.
Weight of Worn Components	2.1 kg	5.4 kg	6 kg	Substantially Equivalent Subject device is lighter, which is desirable.
Service Life	5 years	5 years	5 years	Same
Components / Accessories	2 adjustable shoulder straps with 4 auxiliary strap connectors Battery charging power supplies (3 total) for the two band controllers and the remote Carrying case	Garment cover Battery Battery charging power supply Carrying case	Garment cover Battery AC/DC adapter Roll away travel case	Substantially Equivalent Due to the subject form factor, there are additional accessories available to aid in fit/comfort. This does not raise any new concerns of safety or effectiveness.
Biocompatibility	No direct patient contact. Patient wears over clothes.	No direct patient contact. Patient wears over clothes.	No direct patient contact. Patient wears an undergarment.	Same
Electrical Safety	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC 60601-1-11	EN 60601	ES 60601-1 CAN/CSA C22.2 No. 60601-1 IEC 60601-1-2 IEC 60601-1-11	Substantially Equivalent
Operating Conditions	Temp: + 5˚C to 35˚C Humidity: 15 - 90%, non-condensing	Temp: + 5˚C to 35˚C Humidity: 15 - 93%	Temp – 41 to 95˚F (+ 5˚C to 35˚C) Humidity: 15 - 90%	Substantially Equivalent

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Feature	Subject Device	Predicate Device	Reference Device	Comments
	BreatheBand® System	**IBC AffloVest**	**Hill-Rom Monarch Airway Clearance System**	
	Atmospheric pressure: 70 to 106 kPa	Atmospheric pressure: 70 to 106 kPa	Atmospheric pressure: 70 to 106 kPa	
Storage and Transport Conditions	Temp: 4°F to 140°F (-20°C to 60°C) Relative Humidity: 15% to 90%, non-condensing Atmospheric Pressure: 50 kPa to 106 kPa	Temp: 4°F to 122°F (-20°C to 50°C) Humidity: 15% to 93% non-condensing Atmospheric Pressure: Not Specified	Temp – 4°F to 140°F Humidity : 15% to 90% Atmospheric pressure: 50kPa to 106 kPa	Substantially Equivalent

Discussion of Substantial Equivalence

The BreatheBand® is viewed as substantially equivalent to the predicate and reference devices because:

Indications – The BreatheBand® has similar Indications for Use related to airway clearance via chest wall oscillation.

Discussion: The subject device Indications for Use do not present new concerns of safety or effectiveness.

Patient Population – The subject device is intended for adults 22 years and older. This is a subset of the predicate device.

Environment of Use – The subject, predicate, and reference devices all specify an Environment of Use as a home healthcare setting.

Technology – The subject, predicate, and reference device implement electro-mechanical actuators (motors) to provide therapeutic energy. The predicate uses unbalanced load motors (vibration motors), while the subject and reference devices use linear motors (voice coil motors).

Discussion: The design and technology of the subject device are the same as the reference device and similar to the predicate. All three devices manipulate the user's chest wall through electro-mechanical transduction. The vibration motors of the predicate device are pulsed on and off to simulate percussive forces, while the subject and reference devices produce percussive therapy by reducing the frequency. These slight differences do not present concerns of safety or effectiveness.

Performance – The performance features and parameters were compared to the predicate and reference devices. At the highest intensity settings, the subject device produces force higher than the predicate and lower than the reference. The subject device produces force lower than the predicate or reference device at the lowest settings.

Discussion: Since lower forces at the lowest setting do not present concern for safety or effectiveness (since the subject device can be set for higher intensity if needed for effectiveness) and at the highest setting, the subject produces a force level that is between the levels of the predicate and reference, the performance is substantially equivalent.

Discussion of the Non-clinical Testing Performed:

Testing Against Predicate and Reference Devices:
We performed non-clinical bench testing to demonstrate equivalence to the predicate and reference devices. This testing evaluated force produced by the devices using a load cell and data acquisition. Subject device forces were measured at the mean and extremes of intensity and frequency settings and were compared to the predicate and reference devices to establish equivalence.

Additional Performance Testing:
In addition to the testing against the predicate and reference devices, we conducted several tests to support performance claims for our device. These tests included:
• Wireless coexistence testing to ensure that other sources of wireless interference did not compromise device safety or efficacy.
• Durability testing of the garment cover to evaluate its performance after repeated cleaning.
• Life cycle analysis and simulation for battery use-life to assess the expected longevity of the battery under typical usage conditions.
• Motor use-life testing and analysis to evaluate the durability and performance of the motor over time.
• Usability analysis and evaluations to assess user interaction and ensure ease of use.

Substantial Equivalence Conclusion:

The Exemplar Medical, LLC BreatheBand® can be considered substantially equivalent to the predicate and reference devices.

Substantial Equivalence between the BreatheBand® Model 1000 and the predicate device AffloVest is demonstrated by:

- Substantially equivalent indications statements.
- Identical intended use.
- Similar technological characteristics:
    - Both employ electro-mechanical actuators.

  - Both treat the same anatomic locations of the thorax;
  - Both provide a vibratory, shaking motion to the body; and
  - Both operate over a similar fundamental frequency range.

Substantial Equivalence between the BreatheBand® Model 1000 and the reference device Monarch Airway Clearance System is demonstrated by:

- Substantially equivalent indications statements.
- Identical intended use.
- Identical technological characteristics:
  - Both employ linear motors (voice coil motors);
  - Both treat the same anatomic locations of the thorax;
  - Both provide a vibratory, shaking motion to the body; and
  - Both operate over a similar fundamental frequency range.