April 30, 2026

Tactile Medical
℅ Jessica Buell
Regulatory, Quality, and Compliance Consultant
DuVal & Associates, P.A.
825 Nicollet Mall
Suite 1820, Medical Arts Building
Minneapolis, Minnesota 55402

Re: K252849
Trade/Device Name: AffloVest® Mobile Airway Clearance Therapy
Regulation Number: 21 CFR 868.5665
Regulation Name: Powered Percussor
Regulatory Class: Class II
Product Code: BYI
Dated: September 4, 2025
Received: March 30, 2026

Dear Jessica Buell:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252849

Please provide the device trade name(s).

AffloVest® Mobile Airway Clearance Therapy

Please provide your Indications for Use below.

The 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 AffloVest may be used for the pediatric population (≥6 months of age) to geriatric population.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

Tactile MEDICAL

HEALING RIGHT AT HOME

K252849 - 510(k) Summary

510(k) Owner:

Tactile Medical
3701 Wayzata Blvd, Suite 300
Minneapolis, MN 55416
Contact: Sunday Hoy
612.355.5121
Date prepared: April 28, 2026

Device Name:

Trade Name: AffloVest® Mobile Airway Clearance Therapy
Common Name: Chest-percussion airway secretion-clearing system
Classification Name: Powered Percussor
Regulation: 21 CFR §868.5665
Regulatory Classification: 2
Product Code: BYI

Predicate Device:

Predicate: International Biophysics Corporation AffloVest (K122480)
Reference 1: Hill-rom's Monarch™ Airway Clearance System (K163378)
Reference 2: Baxter's Vest APX System (PVAPX1) (K233441)

Device Description

The 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 AffloVest is a high frequency chest wall oscillation (HFCWO) Vibratory Vest comprised of a vest of synthetic polymer fabric with installed oscillating vibratory motors organized into four zones. It has buckles and straps on the front and over each shoulder that are used to provide the wearer with a snug and evenly distributed fit. Additionally, there is an included charger for the batteries and a controller that is wired into the vest to adjust the intensity of the oscillation on the patient as necessary and as prescribed by a physician.

The AffloVest is constructed of commonly available materials, including urethane-coated nylon, nylon plastic components, DC motors and wires. The vest is powered with a rechargeable lithium-ion battery, which is charged with an A/C power supply. When the vest is powered ON, low voltage DC energy is provided to the vibratory motors, which are in contact with the patient's chest and back, promoting airway clearance.

The AffloVest is intended to be worn over clothing and is made of commonly used fabrics. The product is not intended to directly contact the skin. The vest is the only applied part in the AffloVest system. None of the other parts including the controller and battery that might come into contact with the patient are considered applied parts.

The controller is able to connect to the cloud application over Bluetooth or Wi-Fi to upload usage data and receive over-the-air (OTA) updates. The mobile application connects to the controller via Bluetooth or Wi-Fi to retrieve usage data from the controller. Therapy delivery is not supported by the mobile application. The mobile application is treated as an optional accessory for users that want to access more information about their treatments and other usage data.

Indications for Use

The 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 AffloVest may be used for the pediatric population (≥6 months of age) to geriatric population.

Comparison of Technological Characteristics with the Predicate Devices

The Subject device, the AffloVest Mobile Airway Clearance Therapy, has the same intended use, indications for use, regulatory classification and product code as the Predicate device. The Subject device differs from the Predicate in the connectivity (Wi-Fi and Bluetooth), which technological characteristic is shared with Reference Device 1. The Subject device also differs from the Predicate in the range of garment sizes (16”-75”), which technological characteristic is shared with Reference Device 2. Testing has demonstrated that these minor differences in technological characteristics do not create a new intended use or raise different questions of safety or effectiveness of the Subject device compared to the Predicate device. Thus, the Subject device meets FDA’s criteria for substantial equivalence to the Predicate device. See **Table 1** below for a more detailed comparison of the Subject and Predicate devices.

Table 1: Comparison of Technological Characteristics of Subject and Predicate Devices

Product Feature	**Subject Device (K252849)** **AffloVest Mobile Airway Clearance Therapy**	**Predicate Device (K122480)** **International Biophysics Corporation AffloVest**	**Substantial Equivalence Determination**
Regulatory Classification	21 CFR 868.5665 (Powered Percussor)	Same	Substantially Equivalent
Product Code	BYI (Percussor, Powered-Electric)	Same	Substantially Equivalent

Product Feature	Subject Device (K252849) AffloVest Mobile Airway Clearance Therapy	Predictae Device (K122480) International Biophysics Corporation AffloVest	Substantial Equivalence Determination
Intended Use	The 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. It can be used in a home, hospital, or clinic setting. Not intended to be used in the emergency medical services (EMS) environment.	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.	Substantially Equivalent
Indications for Use	The 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 AffloVest may be used for the pediatric population (≥6 months of age) to geriatric population.	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.	Substantially Equivalent Same as Predicate, with additional clarification of patient population.
Technology of Oscillations	Electromechanical Actuators	Same	Substantially Equivalent
Treatment Modes Available	(1) Treatment type (Drainage, Vibration, or Percussion, (2) Intensity (low/24Hz, medium/26Hz, and high/32Hz), and (3) Duration (5-45 minutes) Percussion: all motors operate in a pulsed fashion Vibration: All motors operate continuously Drainage: All motors operate in a preprogrammed sequential fashion	(1) Treatment type (Drainage, Vibration, or Percussion) (2) Intensity (low/22Hz, medium/25Hz, and high/27Hz). Percussion: all motors operate in a pulsed fashion Vibration: All motors operate continuously Drainage: All motors operate in a preprogrammed sequential fashion	Substantially Equivalent Although the proposed AffloVest has higher frequencies than the predicate and reference devices, similar and even lower forces result during treatment. This is due to the difference in design of the motors. Since the applied forces are similar or lower, there no new questions for safety or effectiveness are raised.

Product Feature	Subject Device (K252849) AffloVest Mobile Airway Clearance Therapy	Predictae Device (K122480) International Biophysics Corporation AffloVest	Substantial Equivalence Determination
Therapy Peak Force Across All Settings	Peak Force (N): 5.7-12.2 (36mm motors) 3.9-4.5 (24mm motors)	Peak Force (N): 4.5 to 7.2	Substantially Equivalent The Subject Device's peak force range is slightly broader than the Predicate Device's force range.
Garment Sizes	16-75 inches	33-53 inches	Substantially Equivalent The Subject Device's vest sizes are a broader range than the Predicate Device to match availability from competitive devices. Performance testing equivalent to what was done for the Predicate was repeated for the Subject Device and raised no new questions of safety or effectiveness.

Performance Data

The AffloVest completed performance testing, including:

- Weight Verification
- Battery Verification
- Carrying Case Life Verification
- Battery Cable Life Testing
- Controller Cable Life Testing
- Vest Functional Testing
- Motor Speed Verification
- Comfort Testing
- Distribution and Environmental Testing
- Keypad Button Life Testing
- Motor Life Testing
- Electrical Safety Testing per IEC 60601-1, 60601-1-6, and 60601-1-11
- Electromagnetic Compatibility Testing per IEC 60601-1-2 and 60601-4-1
- Software Verification and Validation
- Cybersecurity Verification and Validation

Conclusion

The AffloVest Mobile Airway Clearance Therapy continues to meet all its established acceptance criteria that were based upon the performance of the Predicate device. This demonstrates that the device function is as safe, as effective, and performs as well as the Predicate device.

A determination of substantial equivalence requires: 1) the same intended use, and 2) either the same technological characteristics or differences in technological characteristics that do not raise different questions of safety or effectiveness. Both of these conditions have been met and support a determination of substantial equivalence.