October 27, 2026

Tactile Medical
% Mark Spreeman
Regulatory, Quality, and Compliance Consultant
DuVal & Associates, P.A.
Medical Arts Building
825 Nicollet Mall Suite 1820
Minneapolis, MN 55402

Re: K260586
Trade/Device Name: Nimbl™ Pneumatic Compression System
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: September 18, 2026
Received: September 18, 2026

Dear Mark Spreeman:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

NICOLE M. GILLETTE -S

Nicole Gillette
Assistant Director
DHT2B: Division of Circulatory Support,
Structural, and Vascular Devices
OHT2: Office of Cardiovascular 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.	K260586

Please provide the device trade name(s).

Nimbl™ Pneumatic Compression System

Please provide your Indications for Use below.

The Nimbl system is intended for use by medical professionals and patients who are under medical supervision for the treatment of the following conditions:

- ☐ Chronic edema
- ☐ Lipedema
- ☐ Lymphedema
- ☐ Venous insufficiency
- ☐ Wound healing

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

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

510(k) Summary

510(k) Owner: Tactile Medical
3701 Wayzata Blvd
Suite 300
Minneapolis, MN 55416
Contact: Sunday Hoy
612.355.5121

Prepared: October 2026

Device Name: Trade Name: Nimbl™ Pneumatic Compression System
Common Name: Sleeve, Limb, Compressible
Classification Name: Compressible Limb Sleeve
Regulation: 21 CFR §870.5800
Regulatory Classification: 2
Product Code: JOW

Predicate Device: Nimbl™ Pneumatic Compression System (K234155)
Reference Device: Sequential Circulator Model SC-2008-DL (K210417)

Device Description
The Nimbl system is a pneumatic compression device that delivers intermittent sequential compression treatment to affected extremities for chronic edema, lipedema, lymphedema, venous insufficiency, and wound healing.

This device helps direct and move excess fluid from an impaired lymphatic region to healthy regions, where fluid can be absorbed and processed naturally by the body. The Nimbl controller is used to inflate the connected garment chambers in a pre-programmed sequence from the distal end to the proximal end of the garment. The pressure gradient provides higher distal pressures. This creates a dynamic wave of therapy that directs fluid into the lymphatic capillaries while maintaining distal pressure to prevent distal backflow. The patient's healthcare provider determines what pressure setting is appropriate for the patient.

Indications for Use
The Nimbl system is intended for use by medical professionals and patients who are under medical supervision for the treatment of the following conditions:

- Chronic edema
- Lipedema
- Lymphedema
- Venous insufficiency
- Wound healing

Comparison of Technological Characteristics
The Nimbl system has the same Intended Use as the predicate device, and the additional indication of lipedema does not constitute a new Intended Use. The Indications for Use of the Nimbl system are identical to the primary predicate device with the addition of treating patients with lipedema, whereas lipedema is an established condition that the reference device treats.

The Nimbl system also employs the same technological characteristics of either the primary predicate and/or the reference devices with regards to mode of action , principles of operation, environment of use, and physical and functional attributes.

The additional changes to labeling do not create a new Intended Use or raise different questions of safety and effectiveness of the Nimbl system compared to the predicate and reference devices.

Performance Data
The labeling updates to the Nimbl system did not require any clinical or non-clinical performance data. Changes implemented through internal documentation were verified and demonstrated the safety and performance of the Nimbl system:

- Software Verification
- Cybersecurity Testing
- EMC Testing
- Usability Testing
- Design Verification Testing
- Measurements and Pressure Testing
- Distribution and Environmental Testing

Conclusion
Inclusive of this labeling update and the information provided in this submission, the Nimbl system has demonstrated that it is as safe, as effective, and performs as well as the predicate device.

As set out in section 513(i) of the FD&C Act, 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.