October 30, 2025

Merchsource LLC
Shirley Luo
Registered Engineer
7755 Irvine Center Drive SUITE 100
Irvine, California 92618

Re: K251531
Trade/Device Name: AIR COMPRESSION BOOTS 1018195, 1018196
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered inflatable tube massager
Regulatory Class: Class II
Product Code: IRP
Dated: May 19, 2025
Received: May 19, 2025

Dear Shirley Luo:

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,

Tushar Bansal -S

Tushar Bansal, PhD
Acting Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation and
Physical Medicine Devices
OHT5: Office of Neurological and
Physical Medicine 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251531

Device Name
AIR COMPRESSION BOOTS 1018196,1018195

Indications for Use *(Describe)*
The AIR COMPRESSION BOOTS is intended for the temporary relief of minor muscle aches and pains and for temporary increase in blood circulation to the treated areas in people who are in good health. The AIR COMPRESSION BOOTS simulates kneading and stroking of tissues by using an inflatable garment.

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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K251531
510(k) Summary

Prepared on 2025-10-27

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92. This is a traditional 510(K) submission with no previous application.

1. Submitter's Information

Sponsor

- Company Name: Merchsource LLC
- Address: 7755 Irvine Center Drive SUITE 100, Irvine, California 92618
- Phone: +1 949 900 6598
- Contact Person (including title): Shirley Luo
- E-mail: shirley.luo@merchsource.com

Application Correspondent

- Company: Merchsource LLC
- Address: 7755 Irvine Center Drive SUITE 100, Irvine, California 92618
- Tel: 86-13512755282
- Email: jianda-lee@foxmail.com

2. Subject Device Information

- Name of Device: AIR COMPRESSION BOOTS 1018196, 1018195
- Common or Usual Name: AIR COMPRESSION BOOTS
- Regulation Name: Powered inflatable tube massager
- Regulation Number: 21 CFR 890.5650
- Regulatory Class: II
- Product Code: IRP

3. Predicate Device

Predicate Device 1: Rapid Reboot Compression Therapy System, K182668

Predicate Device 2: Air compression therapy system: FO-3001, K201982

4. Device Description

4.1 Overall product description

This product operates through an air pump stored internally, sending air into the air bag, inflating and deflating through the alternate work of the solenoid valve, and squeezing the leg to achieve a massage effect.

4.2 Structure description

This product consists of hand controller, air pump, air valve and leg bag.

4.3 The statement of difference between models

The following model numbers are identical in circuitry and electrical, mechanical and physical construction; the only differences are the size and model number for trading purpose. The model 1018196 is for the 26-inch size and model 1018195 is for the 32-inch size.

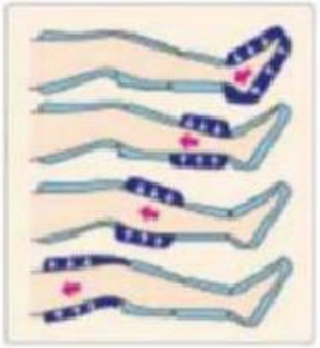
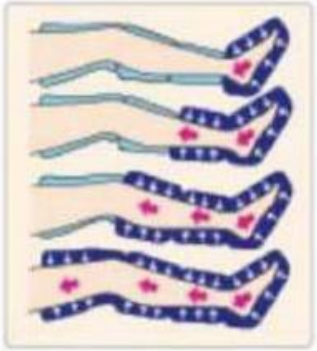
5. Indications for Use

The AIR COMPRESSION BOOTS is intended for the temporary relief of minor muscle aches and pains and for temporary increase in blood circulation to the treated areas in people who are in good health. The AIR COMPRESSION BOOTS simulates kneading and stroking of tissues by using an inflatable garment.

6. Comparison of Technological Characteristics with the Predicate Device

Elements of Comparison	Subject Device	Predicate Device I	Predicate Device 2	Verdict
Company	Merchsource LLC	Rapid Reboot Recovery Products, LLC	FOSHAN HONGFENG CO., LTD.	
Trade Name	AIR COMPRESSION BOOTS	Rapid Reboot Compression Therapy System	Air compression therapy system: FO-3001	--
Regulation Name	Powered inflatable tube massager	Powered inflatable tube massager	Powered inflatable tube massager	Same
510(k) Number	K251531	K182668	K201982	--
Product Code	IRP	IRP	IRP	Same
Regulation Number	21 CFR 890.5650	21 CFR 890.5650	21 CFR 890.5650	Same
Regulatory Class	II	II	II	Same
Review Panel	Physical Medicine	Physical Medicine	Physical Medicine	Same
Rx or OTC	OTC	OTC	OTC	
Indications for Use	The AIR COMPRESSION BOOTS is intended for the temporary relief of minor muscle aches and pains and for temporary increase in blood circulation to the treated areas in people who are in good health. The AIR COMPRESSION BOOTS simulates kneading and stroking of tissues by using an inflatable garment.	The Rapid Reboot Compression Therapy System is intended for the temporary relief of minor muscle aches and pains and for temporary increase in circulation to the treated areas in people who are in good health. The Rapid Reboot Compression Therapy System simulates kneading and stroking of tissues by using an inflatable garment.	Intended for home to temporarily relieve minor muscle aches and/or pains, promote blood circulation in treated areas.	Same

Elements of Comparison	Subject Device	Predicate Device I	Predicate Device 2	Verdict
Treatment Time	User determines therapy time. Choose from 10, 20, or 30 minute session time, with option to add additional 10 minutes to any therapy time.	User determines therapy time. Choose from 10, 20, or 30 minute session time, with option to add additional 10 minutes to any therapy time.	1 - 60mins	Same
Treatment Area	Leg	Leg (including of foot, calf, knee, upper leg).Hip (including of hips, upper leg, glutes, lower lack).Arm (including of entire arm, shoulder, upper chest and back)	Leg	Same
Environment of Use	Clinics, hospital, athlete training, and home environments	Clinics, hospital, athlete training, and home environments	Not provided in the 510k Summary	Same
Modes	5 massage modes Scroll adjustment working mode, from pulse (default)--gradient 5 massage modes: Pulse(default): All zones compress and decompress.	2 modes: "A" mode inflates and deflates chambers from bottom up (distal to proximal), out at a time. "B" mode also inflates chambers from bottom up, but maintains pressure in lower chambers as it works its way to top. Then all	6 chambers: (Normal Mode): Chamber ① inflating till setup pressure or for 2 seconds, then hold air for 2 seconds, start deflating; chamber ② start like chamber ①	Similar Note 1

Elements of Comparison	Subject Device	Predicate Device I	Predicate Device 2	Verdict
	Gradual: Zones compress sequentially, then all decompress. Sequence: Zones compress and decompress sequentially Zones: Select up to 5 zones for targeted pulse massage. Manual: Select up to 5 zones and manually adjust compression.	chambers release pressure at same time once all chambers have sequentially inflated. Mode A  Mode B 	way till chamber ⑥, then rest 3 seconds, then restart chamber ① ②③④⑤⑥ again. (Squeeze Mode): chamber inflating till set up pressure or for 28 seconds, then hold the pressure, chamber ② inflating, till setup pressure or for 28 seconds, then chamber ① hold pressure in same time, then chamber ③ start inflating, same way after chamber ⑥ till Chamber ①②③④⑤⑥ deflating in same time for 3 seconds. Then repeat. (Double Wave Mode): chamber ①② inflating till setup pressure or for 40 seconds, hold air for 2 seconds, then start deflating. Chamber ③④ start inflating till setup pressure or for 40 seconds, hold air for 2 seconds, then deflating, same way for chamber ③④ till chamber ⑤ ⑥, pause for 3 seconds. Then repeat. D (Whole Squeeze Mode): chamber ①②③④⑤⑥ inflating at the same time till setup pressure or for 90 seconds, then deflating in the same time for 3 seconds. Then repeat. E (Combined B + C): sequential squeeze + double wave F (Combined A + C + D): normal + double wave + whole squeeze. 4 and 8 chambers same as 6 chambers above.	
Output Pressure Range	120-210mmHg	0-200 mmHg	30-110mmHg	Similar Note 2
Power Source	100-240V~, 50/60Hz	110VAC, 60Hz	100 - 127V/220 - 240V, 50/60Hz	Similar Note 3
Power	36W	30W	65 W	Similar Note 3

Elements of Comparison	Subject Device	Predicate Device I	Predicate Device 2	Verdict
Number of Chambers	5	4	4, 6, 8	Similar Note 4
Appearance and Size of Control Unit	 207*145*112mm	10" x 6.5" x 5" 	 220*190*113mm	Similar Note 5
Appearance and Size of Boots	 32inch:787*1266mm 26inch:787*1108mm	 X-Short: 14" x 41" Short: 14" x 43" Medium: 14" x 45" Long: 14" x 48" X-Long: 14" x 52" 	 M:91*65cm L:100*74cm XL:110*70cm (Overlapping)	Similar Note 5
Housing Materials	Molded ABS enclosure	Molded ABS enclosure	Molded ABS enclosure	Same

Elements of Comparison	Subject Device	Predicate Device I	Predicate Device 2	Verdict
Compression Applicator Garments Boots/Sleeves /Pants Material	Polyethylene terephthalate (PET)	Nylon with a Polyurethane laminate	Not mentioned in the 510k summary	Different Note 6
Safety Feature	a. Quick press the power button during a massage to begin Decompression. b. The massager will automatically power off after 3 minutes, with boots fully decompressed.	Button on display allows users to stop or pause therapy session at any time	Power button on main unit allows user to stop therapy session at	Same
Mode of Compression	Sequential	Sequential	Sequential	Same
Software/Firmware/ Microprocessor Control	Microprocessor	Microprocessor	Microprocessor	Same
Technology	Compressor and valve system which sequentially inflates cells of inflatable chambers.	Compressor and valve system which sequentially inflates cells of inflatable chambers.	Compressor and valve system which sequentially inflates inflatable chambers.	Same
Standards	IEC 60601-1-2 IEC 60601-1 IEC 60601-1-11 ISO 10993-1	ANSI - AAMI ES 60601 - 1 IEC 60601-1-2 IEC 60601-1-11 ISO 10993-5 ISO 10993-10	IEC 60601 - 1 IEC 60601-1-2 IEC 60601-1-11 ISO 10993-5 ISO 10993-10 ISO 10993-12	Same
Housing Materials And Construction	Molded ABS enclosure	Molded ABS enclosure	Molded ABS enclosure	Same
Patient Contact	Non-conductive attachments	Non-conductive attachments	Non-conductive attachments	Same
Cycle Time	Pulse Mode: 25-30 sec Gradual Mode: 25-30 sec Sequential Mode: 20-30 sec Zones Mode: 25-30 sec Manual Mode: 4-4.5 min	1 min 20 sec	Not provided in the 510k Summary	Different Note 7

Comparison in Detail(s):

Note 1:

The Modes of subject device are similar to those of the cited predicate devices. The subject device have also been demonstrated to comply with the applicable requirements of IEC 60601-1, IEC 60601-1-2, IEC60601-1-11 as well as relevant performance testing. Therefore, this difference does not impact the safety and effectiveness of the device.

Note 2:

The Output Pressure Range of the subject device is similar to that of Predicate Device 1. The subject device has also been demonstrated to comply with the applicable requirements of IEC 60601-1, IEC 60601-1-2, IEC60601-1-11 as well as relevant performance testing. Therefore, this difference does not impact the safety and effectiveness of the device.

Note 3:

The Power Source and Power specifications of the subject device are similar to those of the cited predicate devices. The subject device has been demonstrated to comply with the applicable requirements of IEC 60601- 1, IEC 60601-1-2, IEC60601- 1-11, as well as relevant performance testing. Therefore, this difference does not impact the safety and effectiveness of the device.

Note 4:

The Number of Chambers in the subject device is similar to that of the cited predicate devices. The subject device has been demonstrated to comply with the applicable requirements of IEC 60601- 1, IEC 60601-1-2, IEC60601- 1-11, as well as relevant performance testing. Therefore, this difference does not impact the safety and effectiveness of the device.

Note 5:

The Appearance and Size of the Control Unit and Boots of the subject device is similar to those of the cited predicate devices. The subject device has been demonstrated to comply with the applicable requirements of IEC 60601- 1, IEC 60601-1-2, IEC60601- 1-11, as well as relevant performance testing. Therefore, these differences do not impact the safety and effectiveness of the device.

Note 6:

The compression boots of the subject device are made of polyethylene terephthalate (PET). Although this material differs from those of the cited predicate devices, PET is included in Attachment G, Section B of the FDA guidance “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"”. PET has a documented history of safe use in legally marketed medical devices that contact intact skin (e.g., “The Oligio”, K221989). None of the exclusions listed in Attachment G, Section C apply. Therefore, this material

difference does not impact safety and effectiveness.

Note 7:

The cycle times for the subject device differ from that of Predicate Device 1. The cycle time for Predicate Device 2 is not provided in its 510(k) Summary. The subject device's manual mode has a longer cycle time, while all other therapeutic modes operate with shorter cycles times. The subject device has been demonstrated to comply with the applicable requirements of IEC 60601- 1, IEC 60601-1-2, IEC60601-1-11, as well as relevant performance testing. The cycle times of the subject device are also comparable to other Class II powered inflatable tube massager devices cleared under 21 CFR 890.5650 with product code IRP such as the "Relaxor Perfect Touch Air Massaging System", (K030437) and "NormaTec Pulse and NormaTec Pulse Pro" (K160608), which have similar intended uses and technology. Since FDA has previously cleared devices under the same regulation and product code with comparable intended use, technology, and cycle times without identifying safety or effectiveness concerns, this difference does not impact the safety and effectiveness of the subject device.

7. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

1)Electrical safety and electromagnetic compatibility

The test results demonstrated that the proposed device complies with the following standards:

IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests.

IEC 60601-1 Medical Electrical Equipment Part 1: General requirements for basic safety and essential performance.

IEC 60601-1-11 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

2)Software verification and validation testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's 2023 Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions". The software for this device was developed and reviewed under an Enhanced Documentation Level.

3)Cybersecurity

The subject device does not have any external interfaces. According to FDA's guidance "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices", no further cybersecurity evaluation is needed.

4)Bench Testing

Bench Performance and Safety Testing Report for AIR COMPRESSION BOOTS.
Accelerated Lifecycle Reliability Test Report for AIR COMPRESSION BOOTS.
Post-Reliability Performance Verification Test Report for AIR COMPRESSION BOOTS.

5)Clinical Testing

Clinical testing was not needed for this 510(k). The non-clinical performance testing described above is sufficient to support that the device can be used safely and effectively.

8. Conclusion

The subject device has the same indications for use, core technological characteristics and principles of operation as the cited predicate devices. The technological differences between the subject and predicate devices do not impact safety and effectiveness. The performance data demonstrates that the subject device performs comparably to the predicate devices. Thus the subject device is substantially equivalent to the predicate devices.