August 30, 2024

Therabody, Inc.
℅ Gina Walljasper
Principal Consultant
GPW Enterprises, LLC
47 Gatehouse Rd
Bedminster, New Jersey 07921

Re: K241256
Trade/Device Name: JetBoots PRO Plus
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP, ILY, IRO
Dated: August 7, 2024
Received: August 7, 2024

Dear Gina Walljasper:

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.

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

for Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation and

Rehabilitation Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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)*

K241256

Device Name

JetBoots PRO Plus

Indications for Use *(Describe)*

JetBoots PRO Plus is an air compression therapy device intended to provide graduated pressure to the legs. JetBoots PRO Plus is indicated for the temporary relief of minor muscle aches and pains, and for a temporary increase in blood circulation to the treated area in people who are in good health. JetBoots PRO Plus 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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) PREMARKET NOTIFICATION FOR THERABODY, INC.
JetBoots PRO Plus

510(k) Summary (as required by 807.92)

(1) **SUBMITTER AND OWNER/OPERATOR:**

THERABODY, Inc
1640 S Sepulveda Blvd., Suite 300
Los Angeles, CA 90025
Registration Number: 3012386142
FEI Number: 3012386142
Contact Person: CJ Frederick III, Director, Quality & Regulatory Compliance
Telephone: (484) 888-1290
Email: cj.frederick@therabodycorp.com
Date prepared: May 9, 2024

Application Correspondent:

Contact Person: Gina Walljasper
Company: GPW Enterprises, LLC
Address: 47 Gatehouse Rd., Bedminster, NJ 07921
Tel: (908) 507-6503
Email: gina.gpwconsulting@gmail.com

(2) **DEVICE NAME:**

Trade Name: JetBoots PRO Plus
Common Name: Powered inflatable tube massager
Classification Name: Powered inflatable tube massager
Device Classification: Class II
Review Panel: Neuromodulation and Physical Medicine Devices (DHT5B)
Regulation Number: 21 CFR 890.5650
Product Code: IRP, ILY, IRO

(3) **PREDICATE & REFERENCE DEVICE(S):** Substantial equivalence is based on following legally marketed devices.

Primary Predicate Device

Sponsor	Therabody, Inc. (formerly Theragun, Inc.)
Device Name and Model	RecoveryAir PRO
510(k) Number	K211745
Product Code	IRP
Regulation Number	21 CFR 890.5650
Regulation Class	II

Primary Reference Device

Sponsor	LTBIO Co., Ltd.
Device Name and Model	OLIZ LTB-1000A
510(k) Number	K221189
Product Code	ILY
Regulation Number	21 CFR 890.5500
Regulation Class	II

Secondary Reference Device

Sponsor	Pain Relief Technologies
Device Name and Model	ElectroPulse – Pain Relief
510(k) Number	K062532
Product Code	NUH, ILY, IRO
Regulation Number	21 CFR 882.5890
Regulation Class	II

(4) **DESCRIPTION OF THE DEVICE:**

JetBoots PRO Plus is an air compression therapy device intended to provide graduated pressure to the legs. JetBoots PRO Plus is indicated for the temporary relief of minor muscle aches and pains, and for a temporary increase in blood circulation to the treated area in people who are in good health. JetBoots PRO Plus simulates kneading and stroking of tissues by using an inflatable garment.

JetBoots PRO Plus is two leg shaped garments, one that acts a Lead and the other a Support boot. Each boot is comprised of a console (pressure control unit), a control panel or support power button, and a compression garment in the shape of a boot. The console contains an air pump (compressor) to generate the air pressure, four valves to control the outlet air, a circuit board with embedded firmware to control the pressure, an internal rechargeable battery, and a charging port. The console is fixed to the bottom of the foot on each compression garment, which allows for easy wearing on and off.

Each compression boot has four internal overlapping chambers that can be inflated independently of each other. The device can provide different compression levels in the range from 20mmHg to 100mmHg depending on the user's selection. Hold time is set within the range of 0-10 seconds depending on the preset selected and release time is set by default to 15 seconds.

The lead and support JetBoots PRO Plus boots are each powered by an internal rechargeable battery or by an external DC Power Adapter, plugged into a wall electrical outlet. The batteries are located inside each console and can be charged while the device operates. A 72W medical grade DC power adapter, which is supplied with the device, is powered from the wall electrical outlet (100-240 VAC, 50-60 Hz) and supplies 15.0V, 4.8A. The 72W DC power adapter is able to support both boots to work, charge, and work and charge at the same time if using the splitter cable provided.

The JetBoots PRO Plus are also capable of providing therapeutic warming via the included Light Emitting Diode (LED) Strips. The LEDs emit an infrared light frequency at 850nm and are provided as an optional treatment modality. They can be utilized for a maximum of 45 minutes, either as a standalone therapy or in tandem with the JetBoots PRO Plus' primary device function, pneumatic compression. Therapeutic warming via infrared LEDs is considered to be an "Other Device Function."

The JetBoots PRO Plus also capable of providing therapeutic vibrations via included vibrating pill motors. These are included for an improved user experience and are considered to be an "Other Device Function" that has no impact on the JetBoots PRO Plus' primary device function.

(5) INDICATIONS FOR USE:

JetBoots PRO Plus is an air compression therapy device intended to provide graduated pressure to the legs. JetBoots PRO Plus is indicated for the temporary relief of minor muscle aches and pains, and for a temporary increase in blood circulation to the treated area in people who are in good health. JetBoots PRO Plus simulates kneading and stroking of tissues by using an inflatable garment.

(6) COMPARISON WITH PREDICATE & REFERENCE DEVICES:

The following table is a comparison of Therabody's JetBoots PRO Plus, Predicate and Reference devices.

Therabody's JetBoots PRO Plus is substantially equivalent in terms of the technological characteristics, features, specifications, materials, primary mode of operation and indications for use, to the RecoveryAir PRO, K211745. Comparisons to the Primary Reference Device quoted below, OLIZ LTB-1000A, K221189, as well as the Secondary Reference Device, ElectroPulse – Pain Relief, K062532, demonstrate that the additional modalities of Infrared LED Heat and Therapeutic Vibration do not raise additional concerns of safety and effectiveness. Any differences between the Subject Device, Primary Predicate Device, and Reference Devices do not raise new issues of safety or effectiveness.

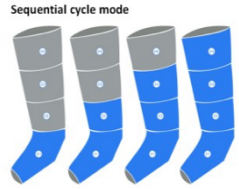
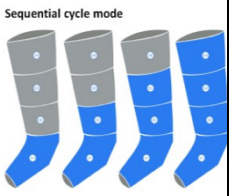
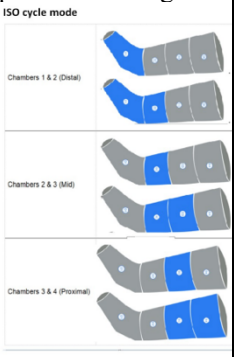
Comparison in Detail(s):

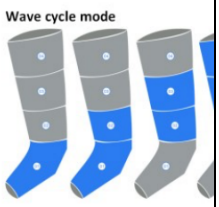
Table 1 General Comparison

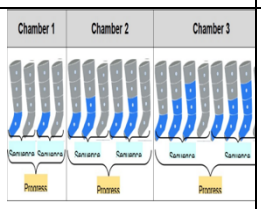
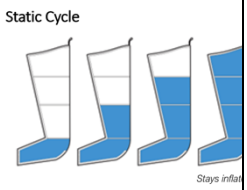
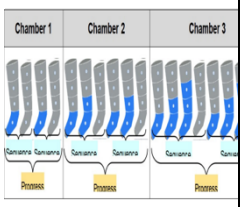
Item	Proposed Device K241256	Primary Predicate Device K211745	Primary Reference Device K221189	Secondary Reference Device K062532	Remark
Manufacturer	Therabody, Inc.	Therabody, Inc. (Formerly Theragun, Inc.)	LTBIO Co., Ltd.	Pain Relief Technologies	
Product Name	JetBoots PRO Plus	RecoveryAir PRO	OLIZ LTB-1000A	ElectroPulse – Pain Relief	
Classification Name	Powered inflatable tube massager	Powered inflatable tube massager	Infrared Lamp	Transcutaneous Electrical Stimulator for Pain Relief	
Product Code	IRP, ILY, IRO	IRP	ILY	NUH, ILY, IRO	Similar
Regulation No.	21CFR 890.5650 21CFR 890.5500	21CFR 890.5650	21CFR 890.5500	21CFR 882.5890	Similar
Class	2	2	2 (Exempt, Underwent 510k)	2	SAME
Indication for Use	JetBoots PRO Plus is an air compression therapy device intended to provide graduated pressure to the legs. JetBoots PRO Plus is indicated for the temporary relief of minor muscle aches and pains, and for a temporary increase in blood circulation to the legs in people who are in good health. JetBoots PRO Plus simulates kneading and stroking of tissues by using an inflatable garment.	The RecoveryAir PRO is an air compression therapy device intended to provide graduated pressure to compression garments. The RecoveryAir PRO is indicated for the temporary relief of minor muscle aches and pains, and for a temporary increase in blood circulation to the treated areas in people who are in good health. The RecoveryAir PRO simulates kneading and stroking of tissues by using an inflatable garment.	The OLIZ LTB-1000A is intended to deliver heat in the IR spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation.	TENS: Used for the temporary relief of pain associated with sore and sching muscles in the lower back due to strain from exercise, or normal household and work activities. Vibration: Relaxing Muscles and relieving minor aches and pains. Heat Lamp: Emits energy at neat infrared frequencies to provide topical heating and to provide temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness, promoting relaxing of muscle tissue, and to temporarily increase local blood circulation.	SAME
Prescription/OTC	OTC	OTC	OTC	OTC	SAME

Table 2 Performance Comparison

Item	Proposed Device	Primary Predicate Device K211745	Primary Reference Device K221189	Secondary Reference Device K062532	Remark
Power Source	Power Adapter: AC Input: 100 – 240V AC, 50/60Hz, DC Output: 15.0V, 4.8A, 72W Or Internal Battery	Power Adapter: AC Input: 100 – 240V AC, 50/60 Hz, 12V or internal battery	Li-ion batteries (3.7v_1800mA x2)	Not provided.	Similar
Dimensions (L*W*H)	Console & Compression boot (Lead or Support, deflated and fully extended): • S-size: 36.8in (L) * 5.3in (W) * 14.8 (H) • M-size: 42.9in (L) * 5.3in (W) * 16.1 (H) • L-size: 46.5in (L) * 5.3in (W) * 16.1 (H)	8.6in (L) *6.7in (W) *5.1in (H)	Not provided.	Not provided.	Similar
Weight	S-size: 6.0lb (per boot) M-size: 6.4lb (per boot) L-size: 6.7lb (per boot)	4.202 pounds	Not provided.	Not provided.	Similar
Housing Materials	Molded PC+ABS Enclosure	Molded ABS Enclosure	Not provided.	Not provided.	Similar
Sleeves	Compression boots sleeves attached to consoles. Sleeves (extended) only: S: 80cm (L)* 37.5 cm (H) M: 95cm (L)* 41.0 cm (H) L: 1050cm (L)* 41.0 cm (H)	RecoveryAir Compression Boots 95*28.7cm	Not provided.	Not provided.	Similar
Number of Chambers	4	4	Not provided.	Not provided.	SAME

Item	Proposed Device	Primary Predicate Device K211745	Primary Reference Device K221189	Secondary Reference Device K062532	Remark
Modes	Sequential, ISO, or Static Flow Cycles Sequential mode that applies a directional massage, starting at the base of the treated area, and progresses upwards towards the torso and then releases.  ISO mode that applies a directional massage to a smaller, user- selected area. The first chamber inflates, and after a few seconds, the second chamber starts to inflate until both chambers reach the set pressure. Then both chambers deflate, and after a pause the process starts again.  Flow cycles Progress 1: first inflate Chamber 1 to target pressure, then hold & release. then go to Progress 2. Progress 2: first inflated Chamber 1 to target	Sequential, ISO or Rehab (wave) Flow Cycles Sequential mode that applies a directional massage, starting at the base of the treated area, and progresses upwards towards the torso and then releases.  ISO mode that applies a directional massage to a smaller, user-selected area. The first chamber inflates, and after a few seconds, the second chamber starts to inflate until both chambers reach the set pressure. Then both chambers deflate, and after a pause the process starts again.  Wave mode: The first chamber inflates, and after a	Not Provided	Not provided.	Similar

Item	Proposed Device	Primary Predicate Device K211745	Primary Reference Device K221189	Secondary Reference Device K062532	Remark
	pressure, then inflate Chamber 2 and hold Chamber 1. when Chamber 2 reach the target pressure, hold chamber 1 & 2 for specified time, then release totally, then go to Progress 3 Progress 3: first inflated Chamber 1 to target pressure, then inflate Chamber 2 and hold Chamber 1. when Chamber 2 reach the target pressure, hold chamber 1 & 2, & start to inflate Chamber 3, when Chamber 3 reach to the target pressure, then hold chamber 1, 2, 3 for specified time then release totally. then go to Progress 4. Progress 4: first inflated Chamber 1 to target pressure, then inflate Chamber 2 and hold Chamber 1. when Chamber 2 reach the target pressure, hold chamber 1 & 2, & start to inflate Chamber 3, when Chamber 3 reach to the target pressure, then hold chamber 1, 2, 3,& start to inflate Chamber 4, when Chamber 4 reach to the target pressure, then hold chamber 1, 2, 3 &4 for specified time then release totally. then go back to Progress 1 again.	few seconds, the 1st and 2nd chamber starts to inflate until both chambers reach the set pressure. Then the deflation on 1st chamber , the 2nd and 3rd chambers starts to inflate until the both chambers reach the set pressure; then deflate the 2nd chambers inflate 3rd and 4th chambers until the both chambers reach the set pressure.  Flow cycles Progress 1: first inflate Chamber 1 to target pressure, then hold & release. then go to Progress 2. Progress 2: first inflated Chamber 1 to target pressure, then inflate Chamber 2 and hold Chamber 1. when Chamber 2 reach the target pressure, hold chamber 1 & 2 for specified time, then release totally, then go to Progress 3 Progress 3: first inflated Chamber 1 to target pressure, then inflate Chamber 2 and hold Chamber 1. when Chamber 2 reach the target pressure,			

Item	Proposed Device	Primary Predicate Device K211745	Primary Reference Device K221189	Secondary Reference Device K062532	Remark
	 Static Cycle The chambers inflate one at the time starting at chamber 1 while maintaining negative gradient of compression along the leg. The pressure is limited to 20 mmHg to 30 mmHg. Once inflated, the chambers do not deflate during the treatment. While the garment is inflated, it comes in contact with the legs to optimize the treatment of vibration and infrared LED light by ensuring optimal contact with the leg. 	hold chamber 1 & 2, & start to inflate Chamber 3, when Chamber 3 reach to the target pressure, then hold chamber 1, 2, 3 for specified time then release totally. then go to Progress 4. Progress 4: first inflated Chamber 1 to target pressure, then inflate Chamber 2 and hold Chamber 1. when Chamber 2 reach the target pressure, hold chamber 1 & 2, & start to inflate Chamber 3, when Chamber 3 reach to the target pressure, then hold chamber 1, 2, 3,& start to inflate Chamber 4, when Chamber 4 reach to the target pressure, then hold chamber 1, 2, 3 &4 for specified time then release totally. then go back to Progress 1 again. 			
Device Pressure Range	20 – 100 mmHg, steps of 5mm Hg	20 – 100 mmHg	Not provided/Not applicable	Not provided/not applicable	SAME
Maximum Device Surface Temperature	43.2° C	Not provided/Not applicable	Less than 40° C	Not provided.	Similar
Highest Measured Skin Temperature During Treatment	36.8° C	Not provided/Not applicable	Not provided	Not provided.	Similar

Item	Proposed Device	Primary Predicate Device K211745	Primary Reference Device K221189	Secondary Reference Device K062532	Remark
Wavelengths	655nm, 850nm	Not provided/Not applicable	655nm, 855nm	Not provided.	SAME
Treatment Time	10min – 60min, steps of 5min for Pneumatic Compression 10min – 45min for Infrared LED	10min – 90min, step of 5min	15 minutes, twice per day. Total of 210 minutes per week.	Not provided.	Similar
Hold time within cycle	0 – 10 seconds depending on the selected preset.	2 – 10 seconds	Not Provided/Not Applicable	Not Provided/Not Applicable	Similar
Pause interval between cycles	15 seconds	10 – 70 seconds	Not Provided/Not Applicable	Not Provided/Not Applicable	Similar
Mobile Application	Device does not connect to a Mobile Application.	Bluetooth Communication	Not Provided	Not Provided	Similar
Patient Contact	Non-conductive appliances	Non-conductive appliances	Not Provided	Not Provided	SAME
Garment Material	Polyether Nylon Fabric	Polyether Nylon Fabric	Not Provided	Not Provided	SAME
Software/Firmware/ Microprocessor Control	Microprocessor	Microprocessor	Not Provided	Not Provided	SAME
Device Function	Compressor and valve system which sequentially inflates cells of appliance, Light Emitting Diodes,	Compressor and valve system which sequentially inflates cells of appliance	Light Emitting Diodes	Not Provided	SAME

Table 3 Safety Comparison

Item	Proposed Device	Primary Predicate Device K211745	Primary Reference Device K221189	Secondary Reference Device K062532	Remark
Electrical Safety	Complies with IEC 60601-1, IEC 60601-1-11	Complies with IEC 60601-1, IEC 60601-1-11	Complies with IEC 60601-1, IEC 60601-1-11	Not Provided.	SAME
Photobiological Safety	Complies with IEC 62471 Complies with IEC 60601-2-57	Does not contain components that required testing to demonstrate Photobiological Safety.	Not Provided	Not Provided.	SAME
EMC	Complies with IEC 60601-1-2 ANSI C63.18-2014	Complies with IEC 60601-1-2	Complies with IEC 60601-1-2	Not Provided.	Similar

Biocompatibility	Complies with ISO 10993-5 and ISO 10993-10 ISO 10993-23	Complies with ISO 10993-5 and ISO 10993-10 ISO 10993-23	Complies with ISO 10993-1 and ISO 10993-5 ISO 10993-10	Not Provided.	SAME
Label and Labeling	Conforms to FDA Regulatory Requirements	Conforms to FDA Regulatory Requirements	Not Provided.	Not Provided.	SAME

(7) **PERFORMANCE DATA**:

The following performance data were provided in support of the substantial equivalence determination, Electrical safety and electromagnetic compatibility (EMC) JetBoots PRO Plus passed all electrical safety and EMC tests, Electrical Safety Testing was conducted in accordance with:

- IEC 60601-1:2005, AMD1:2012 + AMD2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-6:2010 + A1:2013 + A2:2020, Medical devices – Application of usability engineering to medical devices
- IEC 60601-1-11:2015, 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
- IEC 60601-2-83:2019, Medical electrical equipment – Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment
- IEC 62133-2:2017 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications Part 2: Lithium systems
- the Advancement of Medical Instrumentation for the evaluation of Wireless Coexistence

EMC Testing was conducted in accordance with:

- IEC / EN 60601-1-2:2014-02, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic Disturbances – Requirements and Tests
- ANSI C63.18-2014

Sterilization & Shelf-life Testing: JetBoots PRO Plus is not sold sterile or ever intended to be sterilized. Therefore, sterilization testing was not necessary to demonstrate the safety or performance of the device. The subject device has a shelf-life of 1000 hours.

Biocompatibility Testing:
Cytotoxicity, Irritation and Sensitization testing was conducted to demonstrate the biocompatibility of patient-contacting materials of JetBoots PRO Plus in accordance with:

- ISO 10993-5:2009, biological evaluation of medical devices – part 5: tests for in vitro cytotoxicity
- ISO 10993-10:2021, biological evaluation of medical devices - part 10: tests for skin sensitization
- ISO 10993-23:2021, biological evaluation of medical devices - part 23: tests for skin irritation

Software Verification and Validation Testing
Software Verification and Validation Testing was conducted in accordance with IEC 62304:2006 Medical Device Software – Software Life Cycle Processes.

Animal Study
Animal testing was not required to demonstrate safety and effectiveness of JetBoots PRO Plus

Clinical Studies
Clinical testing was not required to demonstrate the safety and effectiveness of the JetBoots PRO Plus.

Non-Clinical Testing
Device Temperature Range Testing was conducted in accordance with "Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Heating and Cooling Devices."

(8) PERFORMANCE TESTING BENCH

The following performance bench testing was conducted:

- Performance test before reliability
- Reliability Bench Test Report
- Performance test after reliability
- Max Pressure Testing for Accuracy During Treatment
- Mechanical Safety Valve Testing
- Air Bladder Testing

Usability Engineering

Usability Study Report, Therabody study TG-RA-Jetboots PRO Plus

(9) **CONCLUSION:**

JetBoots Pro Plus is substantially equivalent to the Primary Predicate Device and the Reference Devices in Indications for Use and technological characteristics. Though minor differences exist between the Proposed, Predicate, and Reference devices, these do not raise questions of safety and effectiveness. Therefore, Therabody's JetBoots PRO Plus is as safe, as effective, and performs as well as the Predicate and Reference Devices.