October 4, 2021

Theragun, Inc.
% Thomas Padula
VP Regulatory Compliance
Schiff & Company, Inc.
583 Mountain Avenue
North Caldwell, New Jersey 07006

Re: K211745
Trade/Device Name: RecoveryAir PRO
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: September 15, 2021
Received: September 16, 2021

Dear Thomas Padula:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Heather Dean, PhD
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211745

Device Name
RecoveryAir PRO

Indications for Use *(Describe)*
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 temporary increase in 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.

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.

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"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) Summary (as required by 807.92)

1) SUBMITTER:

THERAGUN, Inc.
6100 Wilshire Blvd Suite 200 Los
Angeles, CA 90048 Registration
Number: 3012386142
FEI Number: 3012386142
Contact person: CJ Frederick, III (Director, Regulatory Compliance)
Telephone: 310-570-8341
Email: cj.frederick@therabodycorp.com
Date prepared: September 13, 2021

Application Correspondent:
Contact Person: Thomas Padula
Company: Schiff & Company, Inc.
Address: 583 Mountain Avenue, North Caldwell, NJ 07006
Tel: 201-317-8810
Email: thomaspadula@schiffandcompany.com

2) DEVICE NAME:

Trade Name: RecoveryAir PRO
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

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

Items	Primary Predicate Device	Reference Device
Sponsor	Mego Afek AC Ltd	Mego Afek AC Ltd
Device Name and Model	Recovery Pump 737R	Recovery Pump 737R (RPX)
510(k) Number	K140519	K190493
Product Code	IRP	IRP
Regulation Number	21 CFR 890.5650	21 CFR 890.5650
Regulation Class	II	II

4) DESCRIPTION OF THE DEVICE:

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 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 Console (Pressure control unit) supplies air at a regulated pressure to a compression garment worn over the area to be treated. The console contains a compressor which generates the air pressure, valves which control the outlet air, user control panel and firmware which controls the pressure and treatment cycle. The pressure control unit is powered by external DC Power Adapter, plugged into a wall electrical outlet or by a rechargeable battery which can operate the device for more than four hours. The battery is located inside the Console and can be charged while the device operates from a wall electrical outlet.

The Prong Plug is used as a dummy hose plug for sealing the second air outlet to prevent air escape when the other outlet is connected to the pressure garment.

The 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 12 VDC 3A to the Console. The DC power adaptor is also used for charging the Battery.

The Battery Pack is located inside the Console's enclosure is used as backup power. When Battery is fully charged it can power the Console for more than four (4) hours.

The Battery may be charged during normal operation of the console.

The Battery charging time is up to 8 hours.

Smart-phone application uses low power Bluetooth wireless to communicate with the Console. The application enables modifying, storage and display of the device’s treatment parameters, and start/stop treatment via Bluetooth communication, similar to reference device (K190493).

5) INDICATIONS FOR USE:

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 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.

6) COMPARISON WITH PREDICATE DEVICES: Following table is a comparison of RecoveryAir PRO and the predicate devices.

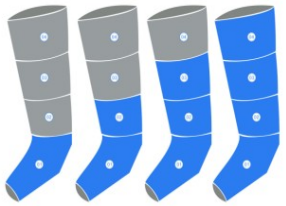
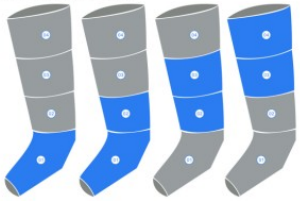
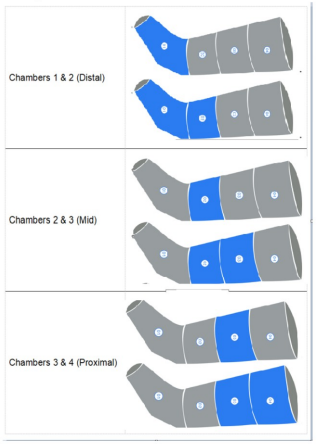
RecoveryAir PRO is substantially equivalent in terms of the technological characteristics, features, specifications, materials, mode of operation and indications for use, and is substantially equivalent to the predicate device quoted below. The differences between the subject device and predicate device do not raise new issues of safety or effectiveness.

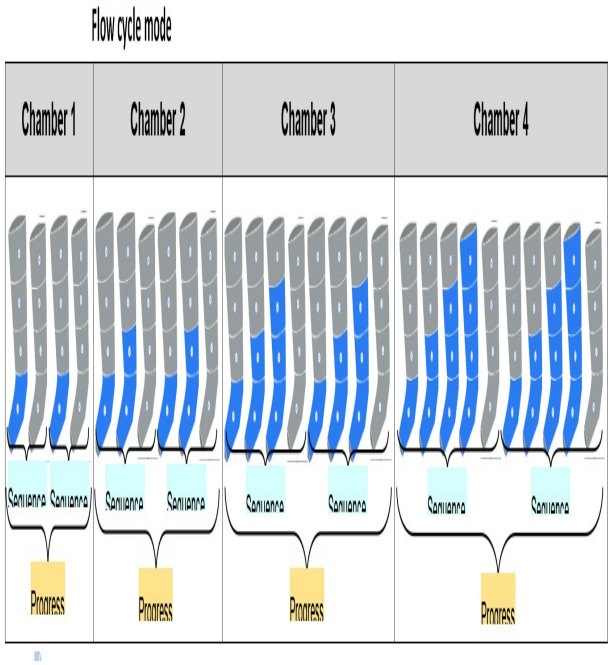
Comparison in Detail(s):

Elements of comparison	Subject Device	Primary Predicate Device	Verdict
Manufacturer	Theragun Inc	Mego Afek AC Ltd	--
510K number	Subject device	K140519	--
Product Name	RecoveryAir PRO (Model RecoveryAir PRO)	Recovery Pump 737R	--
Classification Name	Powered inflatable tube massager	Powered inflatable tube massager	same
Regulation Class	2	2	same
Regulation Number	21 CFR 890.5650	21 CFR 890.5650	same
OTC & Rx	OTC	OTC	same
Indications for Use			
Indications for Use	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 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 Recovery Pump 737R is an air compression therapy device intended to provide graduated pressure to compression garments. The Recovery Pump 737R is indicated 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 Recovery Pump 737R simulates kneading and stroking of tissues by using an inflatable garment.	same

Device design			
Power Source	100-240 V AC, 50/60 Hz, 12 V or internal battery.	Not publicly available	-
Dimensions (W*H*L)	8.6in (L) *6.7in (W) *5.1in (H)	Not publicly available	-
Weight	4.202 pounds	Not publicly available	-
Housing Materials	Molded ABS enclosure	Not publicly available	-
Sleeves	RecoveryAir Compression Boots: 95*28.7 cm	Not publicly available	-
Number of Chambers	4-chamber	Not publicly available	-
Sleeve Materials	Polyether Nylon Fabric	Not publicly available	-
Modes ((Inflation sequences)	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 few seconds,	Not publicly available	

	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, 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.		

Modes (visual description)	Sequential cycle mode  Sequential Rehab (wave) Wave cycle mode  ISO ISO cycle mode  	Not publicly available	

	Flow cycles 		
Device Pressure range	20-100mmHg	Not publicly available	
Treatment Time	10min-90min, step of 5min	Not publicly available	-
Hold time within cycle	2 - 10 sec.	Not publicly available	-

Pause interval - between cycles	10 - 70 Sec.	Not publicly available	-
Mobile application	Bluetooth communication	Not publicly available	-
Patient contact	Non-conductive appliances	Not publicly available	-
Software/Firmware/ Microprocessor Control	Microprocessor	Not publicly available	-
Technology	Compressor and valve system which sequentially inflates cells of appliance	Not publicly available	-
FDA-Recognized Standards			
Electrical safety EMC	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11	Not publicly available	-
Biocompatibility	ISO 10993-5 ISO 10993-10	Not publicly available	-

7) PERFORMANCE DATA:

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

Electrical safety and electromagnetic compatibility (EMC)
RecoveryAir PRO passed all electrical safety and EMC tests.

Electrical Safety Testing was conducted in accordance with:
IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012 (or IEC 60601-1:2012 reprint) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
IEC 60601-1-11:2015, 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 health care environment.
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
ANSI C63.27-2017 American National Standard for 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 Compatibility.

Sterilization & Shelf-life Testing
RecoveryAir PRO is not sterile, therefore sterilization testing was not necessary to demonstrate the safety or performance of the device. The subject device has a shelf-life of 3 years.

Biocompatibility Testing
Cytotoxicity, Irritation and Sensitization testing was conducted to demonstrate the biocompatibility of the patient-contacting materials of RecoveryAir PRO, in accordance with ISO 10993-5:2009, biological evaluation of medical devices -- part 5: tests for in vitro cytotoxicity and ISO 10993-10:2010, biological evaluation of medical devices - part 10: tests for irritation and skin sensitization.

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 RecoveryAir PRO.

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

8) CONCLUSION:

RecoveryAir PRO is substantially equivalent to the predicate device in indications for use and technological characteristics. Any differences that may exist between the subject and predicate devices do not raise questions of safety and effectiveness. Therefore, RecoveryAir PRO is as safe, as effective, and performs as well as the predicate device.