December 22, 2020

Rapid Reboot Recovery Products, LLC
% Prithul Bom
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K203552
Trade/Device Name: Rapid Reboot
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered inflatable tube massager
Regulatory Class: Class II
Product Code: IRP
Dated: December 2, 2020
Received: December 4, 2020

Dear Prithul Bom:

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)*
K203552

Device Name
Rapid Reboot

Indications for Use *(Describe)*
The Rapid Reboot REGEN+, REGEN, or GENESIS Compression Therapy Systems are 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 Rapid Reboot REGEN+, REGEN, or GENESIS Compression Therapy Systems simulate 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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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

I. SUBMITTER

Rapid Reboot Recovery Products, LLC
1396 W 200 S, Building 2, Unit A
Lindon, Utah 84042
Tel: +1.801.704.5271 ext. 405

Contact Person: David Johnson, CEO
Date Prepared: October 7, 2020

II. DEVICE

Name of Device:	Rapid Reboot REGEN+ Rapid Reboot REGEN Rapid Reboot GENESIS
Classification Name:	Powered Inflatable Tube Massager
Regulation:	21 CFR §890.5650
Regulatory Class:	Class II
Product Classification Code:	IRP

III. PREDICATE AND REFERENCE DEVICE

Predicate Manufacturer:	Rapid Reboot Recovery Products, LLC
Predicate Trade Name:	Rapid Reboot Compression Therapy System
Predicate 510(k):	K182668
Reference Manufacturer:	NormaTec Industries, LP
Reference Trade Name:	NormaTec Pulse 2.0 and Pulse Pro 2.0
Reference 510(k):	K183169

IV. DEVICE DESCRIPTION

The Rapid Reboot GENESIS, REGEN, and REGEN+ model systems are powered inflatable tube massagers (Product Code IRP). They are indicated for the temporary relief of minor muscle aches and pains and for the temporary increase in circulation to the treated areas in people who are in good health. They simulate kneading and stroking of tissues by using an inflatable garment. The air pump is connected to the dedicated sleeves via a series of hoses, and each sleeve has four (4) compression chambers. The compression massage direction is from limb end to body center (distal to proximal). By inflating the air chambers sequentially and then deflating as one cycle, the pressure can be adjusted to avoid any discomfort to the user. The sleeve works under the action of sensors and microprocessors. Software controls the timing and pressure reflected by the sensor, cycling airflow into and out of the sleeves to compress the body in a controlled and specific manner. Each unit also has a user interface that allows users the ability to control several aspects of the massage: i.e., intensity (pressure), session duration, and mode. The devices are powered by an external IEC 60601-1 compliant power supply and can also be powered by an internal IEC 62133-compliant lithium-ion battery.

The user interface on the GENESIS, REGEN, and REGEN+ models is a 6” HD LED touchscreen with capacitive sensors identical to most smartphones. The user interface provides for:

- Starting and stopping the massage treatment;
- Adjusting the time, intensity (pressure), and type of distal-to-proximal sequence (Mode).

While the main functions, indications for use, and parameters of settings are the same on the three models, there are differences in non-crucial features and resolution of settings that are intended for marketing differentiation and user preferences: e.g., the REGEN and REGEN+ models offer pressure resolution of 5 mmHg from 0 to 200 mmHg for a total of 40 potential pressure settings, while the GENESIS only offers 7 pressure settings. Similarly, the REGEN and REGEN+ allow the user to set the session duration, or time, to the minute between 1 and 179 minutes (2 hrs and 59 minutes), the GENESIS only allows the user to set a session duration of 10, 20, 30, 40, 50, or 60 minutes.

In addition to the user interface on these respective devices, these proposed models have Bluetooth Low Energy (BLE) capability that allows the use of a Rapid Reboot app to control a device. The app mimics the device interface graphics and buttons, allowing the user to use a compatible Android or iOS powered smartphone or tablet to control the devices core functions just as if they were using the interface on the device. The app functionality is limited to mimicking the device interface and does not provide additional settings that alter the therapy provided by the device. When paired with a REGEN or REGEN+, the app does offer additional, non-critical and non-function related features intended for marketing differentiation and user preferences: e.g., informational features in the menu, programs (i.e., saved settings) that can be saved and quickly applied to future sessions, and the ability to access logs showing usage.

V. INDICATIONS FOR USE

The Rapid Reboot REGEN+, REGEN, or GENESIS Compression Therapy Systems are 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 Rapid Reboot REGEN+, REGEN, or GENESIS Compression Therapy Systems simulate kneading and stroking of tissues by using an inflatable garment.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVCE

The following characteristics were compared between the subject device and the predicate device in order to demonstrate substantial equivalence:

- Indications for Use – The predicate and subject device have identical indications for use. Both are indicated for temporary relief of minor aches and pains and for temporary increase in circulation to treated areas in people who are in good health. They both simulate kneading and stroking of tissues by using an inflatable garment.
- Materials – The predicate and subject device are made of similar patient-contacting materials. The exact materials are different between the subject device and predicate device but biocompatibility testing including cytotoxicity, sensitization, and irritation testing has been completed to demonstrate that the new material is as safe as the predicate device.
- Design – The predicate and subject device have the same fundamental design of an external automated air pump, wearable garments, and software controls. The subject device introduces a new software user interface that has been validated to perform as well as the predicate device.
- Energy Source – The predicate device uses a direct wall outlet plug to power the system. The subject device is powered by 12VDC via an IEC 60601-1 compliant power supply (100-240VAC input) Integrated rechargeable battery. Electrical Safety and EMC testing was conducted to ensure that the change in energy source is as safe and effective as the predicate.

- Other Design Features – The proposed models include a new housing design from the predicate to make them smaller and more portable as well as accommodate the integrated battery and 6" LCD touchscreen.
- Performance Testing – The predicate and subject device involved the following testing:
    - Human Factors Engineering Usability Testing Report
    - Minimum, Interval, and Maximum Air Pressure Test
    - Maximum Electric Current Value Test
    - Maximum Airflow Valve Test
    - Noise Level Test
    - Mode Tests
    - Button and Display Test
    -

	Predicate Device (K182668)	Reference Devices (K183169)	Proposed New Devices	Comment
Model Name 510(k) Number	Rapid Reboot Compression Therapy System	NormaTec Pulse 2.0 and Pulse Pro 2.0	Rapid Reboot REGEN+, REGEN, and GENESIS 510(k): TBD	N/A
Manufacturer	Rapid Reboot Recovery Products, LLC	NormaTec Industries, LP	Rapid Reboot Recovery Products, LLC	N/A
Prescriptive	No, OTC	No, OTC	Same (OTC)	N/A
Indications for Use	The Rapid Reboot Compression Therapy System is indicated for the temporary relief of minor muscle aches and pains and for the temporary increase in circulation to the treated areas in people who are in good health. It simulates kneading and stroking of tissues by using an inflatable garment.	The NormaTec Pulse 2.0 and Pulse Pro 2.0 are air pressure massagers intended to temporarily relieve minor muscles aches and/or pains, and to temporarily increase circulation to the treated areas	Same as predicate	N/A
Intended Use Environment	Clinics, hospital, athlete training, and home environments	Clinics, hospital, athlete training, and home environments	Same	N/A
Power Sources	IEC 60601-1 compliant integrated power panel with 110V direct wall outlet plug	15 VDC via an IEC 60601-1 compliant power supply (100-240VAC input) Integrated rechargeable battery	12VDC via an IEC 60601-1 compliant power supply (100-240VAC input) Integrated rechargeable battery	N/A
Software/Firmware Micro-processor Control	PCB	Microprocessor	Microprocessor	N/A

Technology	Compressor and valve system that sequentially inflates cells of Attachment.	Compressor and valve system that sequentially inflates cells of Attachment. Bluetooth communication ability	Same as reference	Proposed devices incorporate an FCC certified BLE module that allow using the Rapid Reboot app as an additional interface
Compliance with voluntary standards	ES 60601-1, IEC 60601-1-2, IEC 60601-1-11	ES 60601-1 IEC 60601-1-2 IEC 60601-1-11 ANSI C63.27-2017	Same as reference	The proposed devices comply with one additional standard: ANSI C63.27-2017
Device Pressure Range	0-200 mmHg	0-110 mmHg	Same as predicate	N/A
Intensity Control per Chamber	No	Pulse 2.0: Yes (limited range) Pulse Pro 2.0: Yes	GENESIS: Yes (limited range) REGEN: Yes REGEN+: Yes	N/A
Treatment Time	10, 20, 30 minute time settings	Stays on until the user turns it off or can be set up to turn off in a range of 10 minutes to continuous	GENESIS: 10-60 minutes by 10 minute increments REGEN: 1-179 minutes by 1 minute increments REGEN+: 1-179 minutes by 1 minute increments	N/A
Inflation/Deflation Cycle Type	Sequential gradient, peristaltic	Sequential gradient, peristaltic and pulsing	Same as reference	N/A
Attachment Contact Surface Material	Interior: 70 denier with thermoplastic polyurethane laminate/extrusion Exterior: 210 denier with thermoplastic polyurethane laminate/extrusion and rip-stop weave	200 denier nylon with a polyurethane laminate/extrusion	Same as predicate	N/A
Number of Inflatable Attachment Chambers	4	5 or less	Same as predicate	N/A

Weight	5.2 lbs	3.6 lbs (incl. battery)	GENESIS: 4.0 lbs (incl. battery) REGEN: 4.4 lbs (incl. battery) REGEN+: 4.8 lbs (incl. battery)	Differences in weight reflect number of battery packs. GENESIS has one integrated battery pack, REGEN has two, and REGEN+ has three.
Dimensions (W x H x D)	6.5” x 5” x 10”	4.4” x 3.8” x 8.1”	5” x 4.5” x 9.5”	The proposed models include a new housing design from the predicate to make them smaller and more portable, as well as accommodate modification such as an integrated battery and 6” HD LCD touchscreen
Housing Materials and Constructions	Molded ABS enclosure	Molded ABS enclosure	GENESIS: Same REGEN: Same REGEN+: Molded ABS and carbon fiber enclosure	The GENESIS and REGEN control unit housings are comprised of ABS molded parts. The REGEN+ control unit housing is comprised of a combination of molded ABS and carbon fiber parts for marketing differentiation.
Interface	Segment LED capacitive touch display	Pulse 2.0: 4.3” color LCD screen with smart switches Pulse Pro 2.0: 4.3” color TFT Screen with capacitive sensor	GENESIS, REGEN, & REGEN+: 6” color HD LCD touchscreen (1440p X 720p)	
Patient Contact	Non-conductive attachments	Non-conductive attachments	Same	N/A

VII. PERFORMANCE DATA

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

Sterilization & Shelf-life Testing

The device is shelf-stable and not sterile, therefore sterilization and shelf-life testing was not necessary to demonstrate the safety or performance of the device.

Biocompatibility Testing

Cytotoxicity, Irritation, and Sensitization testing was conducted to demonstrate the biocompatibility of the patient-contacting materials of the Rapid Reboot devices.

Electrical safety and electromagnetic compatibility (EMC)

The subject device passed all electrical safety and EMC tests. Electrical Safety Testing was conducted in accordance with IEC 60601-1 Medical Electrical Equipment - General Requirements for Basic Safety and Essential Performance and ANSI IEEE C63.27-2017 American National Standard for Evaluation of Wireless Coexistence. EMC Testing was conducted in accordance with IEC 60601-1-2 General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests.

Software Verification and Validation Testing

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

Mechanical and acoustic Testing

Mechanical Stress Testing was conducted as described above in the performance testing.

Animal Study

Animal performance testing was not required to demonstrate safety and effectiveness of the device.

Clinical Studies

Clinical testing was not required to demonstrate the safety and effectiveness of the Rapid Reboot devices. Instead, substantial equivalence is based upon benchtop performance testing.

Usability Studies

A Usability Study was conducted to ensure that intended users are able to properly use the device as indicated to fulfil its intended use.

VIII. CONCLUSIONS

Rapid Reboot REGEN+, REGEN, and Genesis are substantially equivalent to the legally marketed Rapid Reboot Compression Therapy System (primary predicate) for Indication for Use, and technological and performance characteristics. Based on the Safety and Effectiveness test reports it is at least as safe and effective as the predicate device and technologically comparable. It does not raise any new safety and/or effectiveness concerns. Hence, it is clear that Rapid Reboot is substantially equivalent to that of the predicate device.