December 14, 2018

Rapid Reboot Recovery Products, LLC
% John Gillespy
FDA Consulting, LLC
1100 Del Lago Cir #104
Palm Beach Gardens, Florida 33410

Re: K182668
Trade/Device Name: Rapid Reboot Compression Therapy System
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: September 17, 2018
Received: September 25, 2018

Dear John Gillespy:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vivek J. Pinto -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K182668

Device Name
Rapid Reboot Compression Therapy System

Indications for Use *(Describe)*
The Rapid Reboot Compression Therapy System 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 Rapid Reboot Compression Therapy System 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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510(k) Summary

1. 510(k) Submitter:

Rapid Reboot Recovery Products, LLC
1396 W 200 S Bldg 2A, Lindon, UT 84042
Phone: 801-899-7511
Email: david@rapidreboot.com

2. Company Contact: David Johnson, CEO

3. Date of Submission: September 17, 2018

4. 510(k) Preparer:

John F. Gillespy, MBA
FDA 510k Consulting, LLC
Palm Beach Gardens, FL 33410
Phone: 386-243-4332
Email: john@fda510kconsultants.com

5. Device Classification:

Trade name:	Rapid Reboot Compression Therapy System
Common name:	Powered Inflatable Tube Massager
Device:	Massager, Powered Inflatable Tube
Regulation:	890.5650
Class:	2
Product Code:	IRP

6. Predicate (Primary):

Applicant:	Salton, Inc (Washington, DC)
Device:	Relaxor Perfect Touch Air Massaging System
510(k) Number:	K030437

Predicate (Secondary):

Applicant:	NormaTec Industries, LP (Newton, PA)
Device:	NormaTec Pulse; Norma Tec Pulse Pro
510(k) Number:	K160608

Reference:

Applicant:	Xiamen Senyang Co, Ltd (Xinglin Xiamen, China)
Device:	Pt 1002 Pressure Therapy System
510(k) Number:	K161907

7. Indications For Use… The Rapid Reboot Compression Therapy System 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 Rapid Reboot Compression Therapy System simulates kneading and stroking of tissues by using an inflatable garment.

8. Device Description… Rapid Reboot Compression Therapy System ("Rapid Reboot") consists of an air pump, air pressure sensor, and sleeves working together as one unit. The air pump is connected to the dedicated sleeves via a series of hoses; each sleeve has four (4) compression chambers. The compression massage direction is from limb end to body center. By inflating the air chambers sequentially and then deflating as one cycle, the pressure can be adjusted to avoid any discomfort to the patient. The sleeve works under the action of sensor and microprocessor. Software controls the timing and pressure reflected by the sensor, cycling airflow into and out of the sleeves to compress body

9. Technical Characteristics

Name	**Rapid Reboot Compression Therapy System**
Pressure (mmHg)	0~200 mmHg
Mode	Mode A and Mode B, and the initial is A
Interval	50S
Time(min)	Time 0-30, selection (10, 20, 30min)
Pressure Time	Pressure, 20-200mmHg, Mode A/B, 0-30Min

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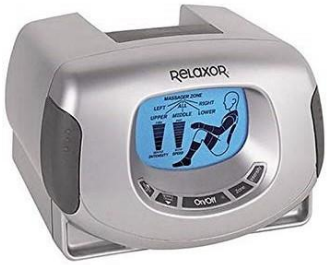
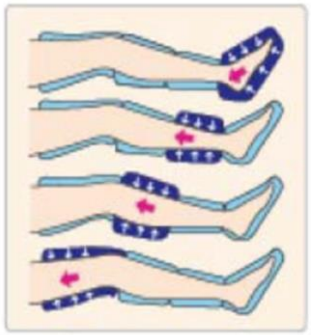
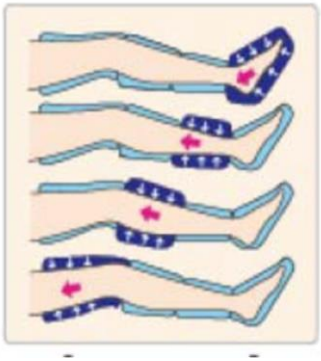
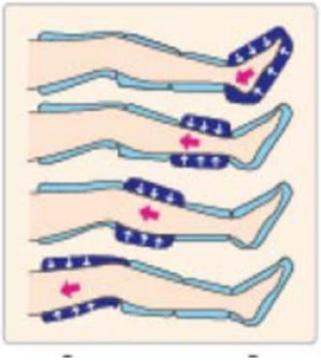
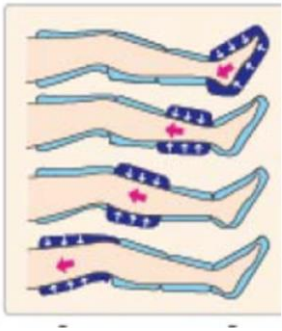
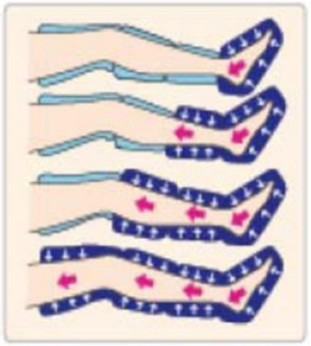
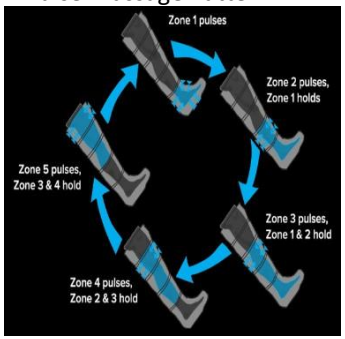
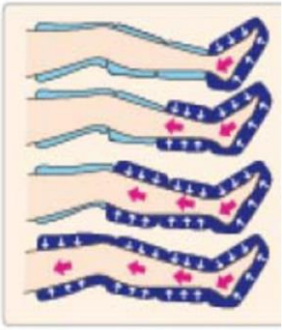
10. Comparison To Predicate

Table 5 – Comparison With Predicate

Device	Subject Device	Primary Predicate	Secondary Predicate	Reference Device	Comparison
Manufacturer	Rapid Reboot Recovery Products, LLC	SALTON, INC	NORMATEC INDUSTRIES, LP	XIAMEN SENYANG CO, LTD	NA
510(k) Number	K182668	K030437	K160608	K161907	NA
Model Name	Rapid Reboot Compression Therapy System	Relaxor Perfect Touch Air Massaging System	NormaTec Pulse and NormaTec Pulse Pro	Pt 1002	NA
Classification	Class II Device, IRP (21 CFR890.5650)	Class II Device, IRP (21 CFR890.5650)	Class II Device, IRP (21 CFR890.5650)	Class II Device, IRP (21 CFR890.5650)	Same
Indications for Use (IFU)	The Rapid Reboot Compression Therapy System is intended 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. The Rapid Reboot Compression Therapy System simulates kneading and stroking of tissues by using an inflatable garment.	The Perfect Touch Air Massaging 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. The Perfect Touch simulates kneading and stroking of tissues by using an inflatable garment.	The NormaTec Pulse and Pulse Pro is an air pressure massager intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas.	Indicated for treatment of medical conditions such as primary lymphedema, edema following trauma and sport injuries, post immobilization edema, venous insufficiencies, lymphedema	Same as Relaxor and NormaTec (predicates).
OTC or Rx	OTC	OTC	OTC	Rx	Same as predicates
Environment of Use:	Clinics, hospital, athlete training, and home environments	Home environment	Clinics, hospital, athlete training, and home environments	Clinics, hospital, athlete training and home environments	Essentially the same

Standards	IEC 60601-1:2014; IEC 60601-1-2:2014; EN ISO 10993-5:2009 & EN ISO 10993-10:2010	Not available	ES 60601-1; IEC 60601-1-2; IEC 60601-1-11	IEC 60601-1:2014; IEC 60601-1-2:2014; EN ISO 10993-5:2009 & EN ISO 10993-10:2010	Meets consensus stds for ES, EMC, Biocompatibility
Mode of Compression	Sequential/Peristaltic	Sequential/Peristaltic	Sequential/Peristaltic and Pulsing	Sequential/Peristaltic	Same except for NormaTec pulsing mode.
Power Source	110 V, 60Hz	120V, 60Hz	100- 240 VAC input	110 V, 60Hz	Same
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.	Has 15 minute sessions.	User determines therapy time, with range of 10 minutes to a continuous session.	User determines therapy time. Choose from 10, 20, or 30 minute session time, with option to add additional 10 minutes to any therapy time.	Same except Normatec allows unrestricted time use.
Max Pressure Min Pressure	0-200 mmHg	80 to 250 mmHg	30-110 mmHg	0-200 mmHg	Same as Xiamen, similar to Relaxor.
Number of Chambers	4 Chambers	12 chambers	5 chambers	4 Chambers	Same except Relaxor has more chambers
Compression Applicator Garments Sleeve Material	Nylon with a Polyurethane laminate	Nylon with a Polyurethane laminate	Nylon with a polyurethane laminate	Nylon with a Polyurethane laminate	Same
Housing Materials And Constructions	Molded ABS enclosure	Molded ABS enclosure	Molded ABS enclosure	Molded ABS enclosure	Same
Patient contact	Non-conductive attachments	Non-conductive attachments	Non-conductive attachments	Non-conductive attachments	Same
Power Consumption	30W	26W	14W	30W	Same

Cycle time	1 min 20 sec	Range of 15 sec to 1 min 5 sec	7 min 10 sec	1 min 20 sec	Same except Relaxor has variable cycle time and Normatec is slightly slower
Size and photo	10” x 6.5” x 5” 	9” x 6” x 6” 	4” x 5” x 9” 	10” x 6.5”x 5” 	All are tabletop or handheld portable
Weight	5.8 pounds	3.2 pounds	3.6 pounds	5.8 pounds	Difference is immaterial
Modes (Inflation sequences, all preprogrammed)	2 modes: "A" mode inflates and deflates chambers from bottom up (distal to proximal chambers), one at a time. "B" mode also inflates chambers from bottom up, but maintains pressure in lower chambers as works its way to top. Then all chambers release pressure at same time once all chambers have sequentially inflated.	1 mode: inflates and deflates chambers from bottom up (distal to proximal chambers), one at a time.	2 different mode settings: “Sequential” mode is same as “A” mode for Rapid Reboot, inflating chambers from bottom up (distal to proximal), one at a time. "Normatec Pulse Massage Pattern" pulses one zone while previous two hold, moving sequentially up extremity.	2 modes: "A" mode inflates and deflates chambers from bottom up (distal to proximal chambers), one at a time. "B" mode also inflates chambers from bottom up, but maintains pressure in lower chambers as works its way to top. Then all chambers release pressure at same time once all chambers have sequentially inflated.	Same as reference device. All devices have sequential mode (distal to proximal chambers).

Modes (visual description)	Mode A: 	Only has one mode. Follows this sequence: 	“Sequential:” 	Mode A: 	Same
	Mode B: 		“Pulse Massage Pattern:” 	Mode B: 	Same as Xiamen. Slight variation with Normatec which holds up to 3 chambers at a time and Rapid Reboot holding up to 4.

"Leg" Attachment	Leg (consisting of foot, calf, knee, upper leg)	Leg (consisting of foot and calf).	Leg (consisting of foot, calf, knee, upper leg).	Leg (consisting or foot, calf, knee, upper leg)	Same
Leg Attachment Photos					Same
Leg Attachment Sizes	X-Short: 14" x 41" Short: 14" x 43" Medium: 14" x 45" Long: 14" x 48" X-Long: 14" x 52" 	One size: 10" x 22"	Short: 14" x 43" Standard: 14" x 48" Tall: 14" x 60" 	Small: 11" x 35" Large: 11" x 43"	Slight variation. Rapid Reboot offers two additional sizes to Normatec, to better suit the anatomy of each user.
"Hip" Attachment	Hip (consisting of upper legs, glutes, hips, lower back)	Back (consisting of lower and mid back)	Hip (consisting of upper legs, glutes, hips, lower back)	Waist (consisting of lower and mid back)	Same as NormaTec
Hip Attachment Photos					Same as NormaTec

Hip Attachment Sizes	Regular: 26” x 32” Large: 26” 35” 	One size: 14” x 40”	One size: 28” x 32”	Small: 15” x 47” Large: 15” x 62”	Slight variation.
“Arm” Attachment	Arm (consisting of entire arm, shoulder, upper chest and back)	Arm (consisting of forearm, lower bicep)	Arm (consisting of entire arm, shoulder, upper chest and back)	Arm (consisting of entire arm, shoulder)	Same as NormaTec
Arm Attachment Photos					Same
Arm Attachment Sizes	Regular: 18” x 38” Long: 18” x 44” 	One size: 8” x “16	One size: 16” x 38” 	Small: 9” x 27” Large: 9” x 35”	Slight variation.
Safety Features	Button on display allows user to stop or pause therapy session at any time.	Button on display allows user to stop or pause therapy session at any time.	Button on display allows user to stop or pause therapy session at any time.	Button on display allows user to stop or pause therapy session at any time.	Same
SW/Firmware/ Microprocessor Control	Microprocessor	Microprocessor	Microprocessor	Microprocessor	Same

Technology	Compressor and valve system which sequentially inflates cells of appliance	Compressor and valve system which sequentially inflates cells of appliance	Compressor and valve system which sequentially inflates cells of appliance	Compressor and valve system which sequentially inflates cells of appliance	Same

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11. Performance Testing… Rapid Reboot has been tested and met the requirements of the following standards:

    1. Electrical Safety – IEC 60601-1:2014… Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
    2. EMC – IEC 60601-1-2:2014… Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests;
    3. Biocompatibility – EN ISO 10993-5:2009… Biological evaluations of medical devices -- Part 5: Tests for In Vitro cytotoxicity
    4. Biocompatibility – EN ISO 10993-10:2010… Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

12. Substantial Equivalence… Rapid Reboot Compression Therapy System is substantially equivalent to the legally marketed Relaxor Perfect Touch Air Massaging System (primary predicate) and Normatec Pulse and Pulse Pro (secondary predicate) for Indication for Use, and it is substantially equivalent in technological and performance characteristics to Pt 1002 Pressure Therapy System (reference device). Based on the Safety and Effectiveness test reports it is at least as safe and effective as the predicate devices and technologically comparable to the reference device, and doesn't raise any new safety and/or effectiveness concerns. Hence, it is clear that Rapid Reboot is substantially equivalent to that of the predicate devices and reference device.