March 5, 2021

Maxstar Industrial Co., Ltd.
% Chris Park
General Manager
Med.com
1809 Holland Dr
Somerset, New Jersey 08873

Re: K191441
Trade/Device Name: Air Relax, Compressible Limb Sleeve System (Model: AR-1.0, AR-2.0)
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: May 24, 2019
Received: May 30, 2019

Dear Chris Park:

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 L. Dean -S

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

510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92

The assigned 510(k) Number: K191441

1. Date of Preparation:02/12/2021

2. Sponsor Identification

Maxstar Industrial Co Ltd
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3. Identification of Proposed Device

Regulatory Information

Trade/proprietary Name	Air Relax/ Compressible Limb Sleeve System
Model No.	AR-1.0, AR-2.0
Common or Usual Name	Powered Inflatable Tube Massager
Regulation Name	Massager, Powered Inflatable Tube
Regulation Number	21 CFR 884.5650
Product Code	IRP (21 CFR 890.5650)
Regulatory Class	Class II

Intended Use Statement:
Air Relax/ Compressible Limb Sleeve System (Model: AR-1.0, AR-2.0) 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 Air Relax/ Compressible Limb Sleeve System (Model: AR-1.0, AR-2.0) simulates kneading and stroking of tissues by using an inflatable garment.

Device Description
AR-1.0, AR-2.0is combined with leg, foot, garments. Leg garment has four air chambers operated by STEP3 controller and foot has one air chamber operated by STEP1. STEP3 controls a leg garment compressing sequentially in order of foot, calf and thigh and then injecting fresh air inside a leg garment through holes of garment to prevent from generating sweat by long wear of a garment.
As this manual includes use methods, maintenance and repair information of a devices, please read carefully for correct use and safe use.

4. Identification of Predicate Device(s)

Primary Predicate device

- K182668
- Trade/Device Name: Rapid Reboot Compression Therapy System
- Company: Rapid Reboot Recovery Products, LLC
- Regulation Number: 21 CFR 890.5650
- Regulation Name: Powered Inflatable Tube Massager
- Regulatory Class: Class II
- Product Code: IRP

Secondary Predicate device

- K193354
- Trade Name: Air Compression Therapy Device
- Model : S9019
- Company: Shenzhen Dongjilian Electronics Co.,Ltd.
- Regulation Number: 21 CFR 890.5650
- Regulation Name: Powered Inflatable Tube Massager
- Regulatory Class: Class II
- Product Code: IRP

5. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device, including

A. Electrical Safety – IEC 60601-1:2014 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
B. EMC – IEC 60601-1-2:2016 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests;
C. 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 healthcare environment
D. Biocompatibility – EN ISO 10993-5:2009 Biological evaluations of medical devices -- Part 5: Tests for In Vitro cytotoxicity
E. Biocompatibility – EN ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

6. Clinical Test Conclusion

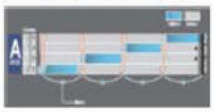
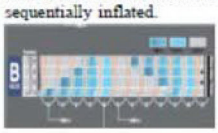
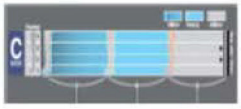
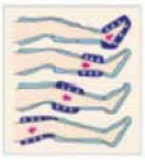
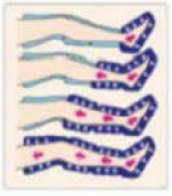
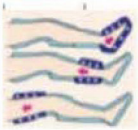
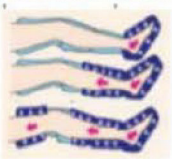
No clinical study is included in this submission.

7. Substantially Equivalent (SE) Comparison

A substantial equivalence table, which summarizes the similarities and differences between our devices, is attached to this section

Table 1 – Comparison With Predicates

Device	Subject Device	Primary Predicate	Secondary Predicate	Comparison
Manufacturer	Maxstar Industrial Co., Ltd.	Rapid Reboot Recovery Products, LLC	Shenzhen Dongjilian Electronics Co.,Ltd.	NA
510(k) Number	Not yet	K182668	K193354	NA
Model Name	AR-1.0, AR-2.0	Rapid Reboot Compression Therapy System	S9019	NA
Classification	Class II Device, IRP (21 CFR890.5650)	Class II Device, IRP (21 CFR890.5650)	Class II Device, IRP (21 CFR890.5650)	Same as all predicates.
Indications for Use (IFU)	The Air Relax/ Compressible limb Sleeve System (AR-1.0, AR-2.0) 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 Air Relax Model AR-1.0/AR-2.0 simulates kneading and	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 Air Compression Therapy Device 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 Air Compression Therapy Device simulates kneading and stroking of tissues by using an inflatable garment	Same as K182668 (Primary predicate) and K193354 (Secondary predicate)
OTC or Rx	OTC	OTC	OTC	Same
Environment of Use:	Clinics, hospital, athlete training, and home environments	Clinics, hospital, athlete training, and home environments	Clinics, hospital, athlete training, and home environments	Same as K182668 (Primary predicate) and K193354 (Secondary predicate)
Standards	IEC 60601-1 IEC 60601-1-2 ISO 10993-5 ISO 10993-10 IEC 60601-1-11	IEC 60601-1 IEC 60601-1-2 ISO 10993-5 ISO 10993-10	IEC 60601-1 IEC 60601-1-2 ISO 10993-5 ISO 10993-10 IEC 60601-1-11	Same
Mode of Compression	Sequential/Peristaltic	Sequential/Peristaltic	Sequential/Peristaltic	Same
Power Source	120 V, 60Hz	110 V, 60Hz	100~240V, 50/60Hz	Simmilar Note 1
Therapy Time	Has 15 minute sessions.	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 20 minute sessions.	Similar with Primary predicate. Sesson time is less than Secondary predicate Note 2
Max Pressure Min Pressure	0-230 mmHg	0-200 mmHg	0 to 240 mmHg	Lower then K193354 (Secondary predicates) Little higher then K182668 (primary predicate) Note 3
Number of Chambers	4 Chambers	4 Chambers	3 chambers	Same as Primary predicate
Compression Applicator Garments Sleeve Material	Nylon with a Polyurethane laminate	Nylon with a Polyurethane laminate	Nylon with a Polyurethane laminate	Same

Housing Materials And Constructions	Molded ABS enclosure Orange: AR-1.0 Navy: AR-2.0	Molded ABS enclosure	Molded ABS enclosure	Same types of housing material
Patient contact	Non-conductive attachments	Non-conductive attachments	Non-conductive attachments	Same
Power Consumption	60VA	30W	12W	Similar as Primary and Secondary predicate Note 4
Size and photo	240 x 190 x 120/mm 	10" x 6.5" x 5" 	10.2 x 5.9 x 25.6 (in) 	Similar with Primary predicate and secondary predicate Note 5
Weight	2.3kg	5.8 pounds	4.6 pounds	
Modes (Inflation sequences, all preprogrammed) (visual description)	3 mode "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.  "C"mode is inflates all chambers and maintained pressure at same time and release pressure all chambers. 	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. 	3 mode Mode 1: Starting with the foot chamber and progressing up the thigh chamber, each section compresses and the pressure gradually rises to the pre-determined air pressure level, then decompresses.  Mode 2: Starting with the foot chamber and progressing up the thigh, each section compresses and the pressure gradually rises to the pre-determined air pressure level, holds the air until the entire garment is compressed. All three sections then decompress simultaneously. Mode 3: include two stage,  stage 1: it work according to the method of mode 1, after the stage 1 is completed, it go to stage 2	Similar with Primary predicate and secondary predicate Note 6

"Leg" Attachment	Leg (consisting of foot, calf, knee, upper leg)	Leg (consisting of foot, calf, knee, upper leg), Arm, Hip	Leg (consisting of foot and calf).	Similar with Primary predicate and secondary predicate Note 7
Leg Attachment Sizes	Sleeve (L) : 320*740 (mm) Sleeve (XL): 390*890 (mm) Sleeve (XXL) : 390*990 (mm)	X-Short: 14" x 41" Short: 14" x 43" Medium: 14" x 45" Long: 14" x 48" X-Long: 14" x 52"	Sleeve : 260x730 (mm)	Similar with Primary predicate and secondary predicate Note 7
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.	Standby button allows user to stop therapy session at any time	Same
SW/Firmware/ 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	Same

The Air Relax/ Compressible Limb Sleeve System (Model: AR-1.0, AR-2.0) has been compared with Rapid Reboot Compression Therapy System (K182668), Air Compression Therapy Device (K193354). The subject device has same intended use and principle of operation, similar technological characteristics as that of predicate devices. Although there are several specifications that are different between the subject device and predicate devices, the comparison analysis has been completed to demonstrate that the differences between these parameters would not adversely impact the safety and effectiveness of the subject device. The subject device has undergone safety and performance tests, and the results complied with the test requests. Therefore, the difference between the subject device and the predicate devices do not raise any problem of substantial equivalence. The subject devices is substantially equivalent to the predicate devices in safety and performance claims.

Substantially Equivalent (SE) Conclusion

Air Relax/ Compressible Limb Sleeve System (Model: AR-1.0, AR-2.0) is substantially equivalent to the legally marketed the product (Rapid Reboot Compression Therapy System / Primary predicate and Air Compression Therapy Device S9019 / Secondary predicate) / in indication for use and similarly so it is mostly substantially equivalent in technological and performance characteristics.

Based on the Safety and Effectiveness test reports it is at least as safe and effective as the all 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 Air Relax/ Compressible Limb Sleeve System (Model: AR-1.0, AR-2.0) is substantially equivalent to that of the predicate devices.