October 21, 2020

Hanuri Distribution, Inc
Jung Moon
President
9601 Owensmouth Ave. # 8
Chatsworth, California 91311

Re: K202044
Trade/Device Name: Powerpress Recovery Unit
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: July 13, 2020
Received: July 23, 2020

Dear Jung Moon:

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,

Amber Ballard, PhD
Assistant Director
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)*

Device Name
POWERPRESS RECOVERY UNIT

Indications for Use *(Describe)*
The Powerpress Recovery Unit 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 Powerpress Recovery Unit 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

(as required by 21 CFR 807.92)

A. 510K Number : K202044

B. Date: October 20, 2020

C. Applicant

Company & Manufacturer Name: Hanuri Distribution, Inc
Address: 9601 Owensmouth Ave. # 8 Chatsworth, CA 91311 USA
Owner & Contact Person: Jung H Moon
Phone: 818-998-1023, Fax: 818-998-0277
Email: info@air1000.com

D. Regulatory Information

1. Proprietary/Trade Name: Powerpress Recovery Unit
2. Regulation Name (Common/Usual Name): Powered inflatable tube massager
3. Regulation Number: 21 CFR 890.5650
4. Product Code: IRP
5. Regulatory Class: Class II

E. Indications for Use

The Powerpress Recovery Unit 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 Powerpress Recovery Unit simulates kneading and stroking of tissues by using an inflatable garment.

F. Environment of Use:

Home, Athlete Training and Clinics environments

G. Warning:

Do not use the compressor to direct pressurized air towards your eyes, nose, mouth, or ears. Doing so may lead to a serious injury

H. Predicate Device

Powerpress Recovery Unit is substantially equivalent to the following

Predicate Device	Manufacturer	510(k)#
DJS Massager; Recovery Pump 701-E; Recovery Pump 701RA	MEGO AFEK AC LTD	K112479

I. Device Description

Powerpress Recovery Unit is a sequential pneumatic compression device designed to apply compression to a limb. The device is composed of two components.

- Pneumatic Manual / Analog Pump
- Limb Sleeve or garment composes of 4 chambers

Powerpress Recovery Unit enables different treatment pressure (30 ~ 100mmHg). When activated, air flows into chamber, the pump provides gradient pressurization to the chambers (sequential inflation of distal to proximal, with distal chambers inflated to a greater pressure than the proximal ones).

After each chamber is inflated, the pressure is held constant until all chambers are inflated, in order to prevent reverse gradient flow. Once all chambers are inflated, they are then all released simultaneously, and the cycle repeats. Pressure within chambers are adjustable – pressure to chamber 1 is controlled by user-adjusted regulator on the pump. Pressure in chamber 2, 3 & 4 are individually lowered according to the default factory setting.

Gradient: appx 7%, example: Foot 60mmHg – Ankle 56mmHg – Calf 52mmHg - Thigh 48mmHg
Cycle Time: Inflation 36 sec / Deflation 24 sec
Inflation time each chamber : 1st chamber(foot) – 36 sec, 2nd chamber(ankle) – 27 sec, 3rd chamber(calf) – 18 sec, 4th chamber(thigh) – 9 sec

A calibrated dial gauge displays pressure in the range of 0 ~ 160 mmHg

J. Substantial Equivalence of Technological Characteristics

Powerpress Recovery Unit Model PR1000 Massage Systems and the predicate device all provide sequential inflation pressure from distal to proximal segments. Both the Powerpress Recovery Unit and predicate devices offer adjustable pressure ranges.

The Powerpress Recovery Unit have decreasing gradient pressures from distal to proximal segments,while predicate device does not have decreasing gradient pressures. The Powerpress Recovery Unit provide continuously adjustable pressure in the range between 30 to 100 mmHg, while the predicate device provides three pressure adjustments options in increments of low, medium and high pressure ranges within the 20 to 80 mmHg range. The Powerpress Recovery Unit have fixed cycle times that are fixed by a motorized valve, and are independent of garment size and number (one or two garments). The predicate device does not have a motorized valve and uses back pressure to trigger the cycle to the next chamber of the garment.

A difference in the subject device from the predicate is that the Powerpress recovery unit has a pressure range from 30 mmHg to 100 mmHg while predicate device has from 20 mmHg to 80 mmHg. But there are FDA cleared devices for same intended use, which are shown in the table below, prove that our pressure range raises no new questions of safety and effectiveness. Also Electrical Safety Test (IEC 60601-1:2005+AMD1:2012) verifies that the technological differences in the fuse rating, power consumption, electric power plug, size and net weight of device do not raise different questions of safety and effectiveness.

MANUFACTURER	510(k) Number	TRADE NAME	PRESSURE RANGE	PRESCRIPTION OR OTC
MEGO AFEK AC LTD	K140519	Recovery Pump 737R	20 mmHg to 100 mmHg	OTC
NormaTec Industries, LP	K160608	NormaTec Pulse and NormaTec Pulse Pro	30 mmHg to 110 mmHg	OTC

The Powerpress Recovery Unit operate within clinically-established parameters. The differences between the predicate and the applicant devices do not impact safety or effectiveness. A table illustrating the substantial equivalence comparison table is provided below.

K. Substantial Equivalence Comparison Table

	Subject Device	**Predicate Device**	**Comment**
Manufacturer	Hanuri Distribution, Inc	MEGO AFEK AC LTD	Different
510(k) Number	K202044	K112479	N/A
Proprietary / Trade Name	Powerpress Recovery Unit	DJS Recovery Pump 701RA	Different
Regulation Name	Powered Inflatable Tube Massager	Powered Inflatable Tube Massager	Identical
Regulation Number	21 CFR 890.5650	21 CFR 890.5650	Identical
Product Code	IRP	IRP	Identical
Regulatory Class	II	II	Identical
Indications for Use	The Powerpress Recovery Unit 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 Powerpress Recovery Unit simulates kneading and stroking of tissues by using inflatable garment.	The DJS Massager 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 DJS Massager simulates kneading and stroking of tissues by using inflatable garment.	Identical
Contraindications	* Do not use this product if you are experiencing inflammation, an infection, pain of unknown origin, or bleeding (internal or external) at or near the site of application or if you have a wound at or near the site of application. * Do not use this product if you are under the care of a physician or have a condition requiring the use of any medical device. * Do not use this product on sensitive skin or on in the presence of poor circulation. * Do not use this product if you have any of the following conditions: o Acute pulmonary edema o Acute thrombophlebitis o Acute congestive cardiac failure o Acute infections	*This device is intended for use by people in good health. This device is not recommended for people who have heart problems, or vascular problems, have a condition requiring the use of any medical device, or have any condition that might affect their normal well being. *If you are, or may be, pregnant, consult with your physician before use. *Do not use this device over insensitive or numb areas, or phlebitis. This device should not be used over swollen or inflamed areas or skin eruptions. Do not use in the presence of unexplained calf pain. *Consult your physician prior to use	Similar

	o Deep Vein Thrombosis (DVT) o Episodes of Pulmonary embolism o Wounds lesions or tumors at or in the vicinity of application o Where increased venous and lymphatic return is undesirable o Bone fractures or dislocations at or in the vicinity of application o Please consult a physician before using this device if: a) If you are pregnant for feel weak b) If you have an implant at the site of application c) If you have a cardiac pacemaker		
Prescriptive or OTC	OTC	OTC	Identical
Pressure Range	30 - 100 mmHg	20 – 80 mmHg	Similar
Time Setting	No Timer, Continuous Mode	No Timer, Continuous Mode	Identical
Compression Mode	Gradient Sequential	Gradient Sequential	Identical
Number of Mode	1 Mode	1 Mode	Identical
Chamber of Garment	4 Chamber (Air Compartments Garment) Overlap Each Chamber	4 Chamber (Air Compartments Garment) Overlap Each Chamber	Identical
Treatment Time	15 min to 45 min	15 min to 45 min	Identical
Pressure Lock Button	YES	YES	Identical
Single or Double Garment Available	YES	YES	Identical
Overload Protection Fuses	This device is equipped with two overload fuses, on each of the power lines	This device is equipped with two overload fuses, on each of the power lines	Identical
Size of Device	H 5.12” x L 11.81” x W 8.27”	H 3.9” x L 10.2” x W 5.1”	Similar
Net Weight	4.5 LBS	5.1 LBS	Similar
Power Consumption	20 watts	11 watts	Similar
Power Source(s)	115V / 50 or 60 Hz	115V / 50 or 60 Hz	Identical
Fuse Rating	0.5 A	2 A	Similar
Electric Plug	2 Prong Plug	Three-pin Plug	Similar
Software	Manual / Analog (not software driven)	Manual / Analog (not software driven)	Identical
Material of Garments	200 denier nylon with a Polyurethane	200 denier nylon with a Polyurethane	Identical

L. Compression Garment Description

a) List all types of compression garments

Half Leg Garment Large Item No. 1016
Half Leg Garment X Large Item No. 1016-A
Full Leg Garment Large Item No. 1014
Full Leg Garment X Large Item No. 1014-A

b) Description of every type of compression garment

1. Half Leg Garment Large Item No. 1016
   4 Chamber Overlapping Sequential Compression Garment
   Length from Floor to Top 19.5" / Length from Ankle to Top 18"
   Top (Knee) Circumference Measurement: 20"
   Mid Calf Circumference Measurement: 18"
   Ankle Circumference Measurement: 15"

2. Half Leg Garment X Large Item No. 1016-A
   4 Chamber Overlapping Sequential Compression Garment
   Length from Floor to Top 19.5" / Length from Ankle to Top 18"
   Top (Knee) Circumference Measurement: 25"
   Mid Calf Circumference Measurement: 23"
   Ankle Circumference Measurement: 19"

3. Full Leg Garment Large Item No. 1014
   4 Chamber Overlapping Sequential Compression Garment
   Length from Floor to Top 30" / Length from Ankle to Top 28"
   Top (Mid Thigh) Circumference Measurement: 24"
   Knee Circumference Measurement: 20"
   Mid Calf Circumference Measurement: 18"
   Ankle Circumference Measurement: 15"

4. Full Leg Garment Large Item No. 1014-A
   4 Chamber Overlapping Sequential Compression Garment
   Length from Floor to Top 30" / Length from Ankle to Top 28"
   Top (Mid Thigh) Circumference Measurement: 30"
   Knee Circumference Measurement: 25"
   Mid Calf Circumference Measurement: 23"
   Ankle Circumference Measurement: 19"

c) Identify whether each type of compression garment you intend to market with your device has received prior 510(k) clearance or has not received prior 510(k) clearance

All of above compression garment has received prior 510(k) clearance. 510(k) number K110276

M. Technological Characteristics

The manufacturer believes that the technological characteristic of the Powerpress Recovery Unit is substantially similar to those of the predicate devices.

Powerpress Recovery Unit has very similar components to its predicate devices and very similar principles of operation.

N. Performance Testing

Bench:

The device has been tested to the requirements of the following standards:

- IEC 60601-1:2005+AMD1:2012

Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

- IEC 60601-1-2: 2014

Collateral standard: Electromagnetic Compatibility – Requirements and Tests

- IEC 60601-1-6:2010+AMD1:2013

Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

- IEC 60601-1-11: 2015

Collateral standard: requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

- ISO 10993
  Compression Garment Skin Sensitization Test Report

Animal:
No animal testing was performed

Clinical:
No clinical testing was performed

O. Conclusion

Powerpress recovery unit is substantially equivalent to the predicates in: indications for use, contraindications, patient population, environment of use, technology characteristics, materials, specifications / performance and compliance with international standards. Minor differences as detailed in the Substantial Equivalence of Technological Characteristics above do not raise questions of safety and effectiveness.