June 22, 2020

Shenzhen Lifotronic Technology Co., Ltd.
% You Yijie
Manager
Qimmiq Medical Consulting Service Co., Ltd
RM. 1711, Building K, NO. 101 Science Ave International
Creative Valley
Guangzhou, Guangdong, 510663 China

Re: K192466
Trade/Device Name: Air Compression Therapy System, Model: Airpro-690
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: January 18, 2020
Received: January 22, 2020

Dear You Yijie:

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 (Acting)
THT5B4: Neurodegenerative 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192466

Device Name
Air Compression Therapy System, Model: Airpro-690

Indications for Use *(Describe)*
Airpro-690 is intended for use by medical professionals and patients at home, who are under medical supervision, in treating many conditions, such as Primary lymphedema, Edema following trauma and sport injuries, Post immobilization edema, Venous insufficiencies, Lymphedema.

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. Submitter's Information

Establishment Registration Information
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Date to prepare: 8/13/2019

2. Device Information

Type of 510(K) submission: Traditional
Trade Name: Air Compression Therapy System
Model: Airpro-690
Common name: Compression Therapy Device
Classification Name: massager, powered inflatable tube.
Regulation Description: Powered inflatable tube massager.
Review panel: Physical Medicine
Product code: IRP
Regulation Class: II
Regulation Number: 21 CFR 890.5650

3. Predicate Device Information

510(k) submitter/holder: DAESING MAREF CO LTD
510(K) Number: K102320
Device: Compressible Limb Therapy System
Trade name: LX7(V7)
Classification Name: massager, powered inflatable tube.
Regulation Description: Powered inflatable tube massager.

Review panel: Physical Medicine
Product code: IRP
Regulation Class: II
Regulation Number: 21 CFR 890.5650

4. Device description

Air Compression System include the host, sleeves, and the air tube to connect them together. Through a multi-chamber inflatable sleeve orderly conducting of rhythmic squeezing inflation and deflation, it cyclic pressure on limb tissue, so as to promote venous blood return, enhance arterial infusion, improve blood circulation and lymphatic circulation. Two port on the back of the controller, labeling as Channel 1/2. And four air ways on each channel. The two channels can work independently, or simultaneously. The system can identify the channel and type of wearing sleeves automatically. If two channels were connected with sleeves, the system will inflate 1/2 channel simultaneously. Treatment Time, pressure, Channel and Treatment Mode are all can be adjusted on Parameter Settings Interface of the main unit.

5. Principle of operation:

The Air Compression Therapy System, model Airpro-690 is a pneumatic compression device and designed to apply pneumatic compression to limbs to treat conditions. It works by inflating and deflating the sleeve sequentially to develop the circulating pressure on the limbs and organization. Squeezing the proximal and distal of the limbs to promote the flow of the blood and lymphatic system, and improve the microcirculation. The System consists of the main unit, the Tubing Sets and sleeves.

6. Indications for Use

Airpro-690 is intended for use by medical professionals and patients at home, who are under medical supervision, in treating many conditions, such as Primary lymphedema, Edema following trauma and sport injuries, Post immobilization edema, Venous insufficiencies, Lymphedema.

7. Summary of technological characteristics of device compared to the predicate devices (K102320)

Characteristic	**Subject device Present application (Air Compression Therapy System, model Airpro-690)**	**Predicate device (K102320, Compressible Limb Therapy System, Model LX7(V7))**	**Discussion of difference**
Classification	21 CFR 890.5650	21 CFR 890.5650	**Same**
Product Code	IRP	IRP	**Same**
FDA Class	2	2	**Same**
Intended Use	Airpro-690 is intended for use by medical professionals and patients at home, who are under medical supervision, in treating many conditions, such as Primary lymphedema, Edema following trauma and sport injuries, Post immobilization edema,	LX7(V7) is intended for use by medical professionals and patients at home, who are under medical supervision, in treating many conditions, such as Primary lymphedema, Edema following trauma and sport injuries, Post immobilization edema,	**Same**

	Venous insufficiencies, Lymphedema.	Venous insufficiencies, Lymphedema.	
Principle of operation	intermittent pneumatic compression device	intermittent pneumatic compression device	**Same**
target population	adults	adults	**Same**
anatomical site	Leg	Leg	**Same**
Material of Patient contact components	**Sleeve:** Nylon	**Sleeve:** Nylon	**Same** Sleeve was demonstrated biocompability safety by passing ISO 10993-5 and ISO 10993-10 tests. The difference does not raise the issue of product's safety and effectiveness.
where used	home	home	**Same**
Design	Desk type	Desk type	**Same**
Power Source	a.c. 120V, 60Hz	Electricity Supply: 230 V~,50/60 Hz Electricity consumption: 50 VA	**Similar** The proposed device was demonstrated electrical safety by passing ANSI/ AAMI ES60601-1: 2005+ A1: 2012 test. The difference in power source does not raise any question in regards to safety and effectiveness.
ANSI AAMI ES60601-1	Yes	Yes	**Same**
IEC 60601-1-2	Yes	Yes	**Same**
Weight	3.5 Kg	2Kg(main system only)	**Different** The Weight will not affect the safety and effectiveness of the proposed device
Dimensions (W x H x D)	235mm(L)×185mm(W)× 190mm(H)	260(W) * 160(D) * 120(H)mm	**Different** The dimensions will not affect the safety and effectiveness of the proposed device
Number of Chamber	4chambers，8chambers	4chambers，8chambers	**Same**
Related power	55VA	50VA	**Similar** The proposed device was demonstrated electrical safety by passing ANSI/ AAMI ES60601-1: 2005+ A1: 2012 test. The difference in power does not raise any question in regards to safety and effectiveness.
Mode of Compression	Sequential	Sequential	**Same**
Mode description	3 modes	3 modes	**Same**
Pressure range	0~180mmHg	0~230mmHg (Air pump pressure range)	**Similar** The pressure range for proposed device is smaller than the one for LX7(V7).

		60~120mmHg (Recommended operating pressure range) (unit of pressure increment : 20mmHg)	Additional risks not concerns for safety and effectiveness.
Operating Time/Therapy Time	10, 20, 30minutes	10~30minutes	**Similar**
Compression Cycle Time	30min	30min	**Same**

8. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Non-clinical verification testing of the Air Compression Therapy System, model: Airpro-690 included electrical, mechanical, and software tests to show the device meets its design specifications. Validation and performance testing validates that the device meets its user needs. Verification and validation test results established that the device meets its intended use, that it is as safe, as effective, and performs as well as the predicate devices, and that no new issues of safety and effectiveness were raised. The Air Compression Therapy System, model: Airpro-690 was designed, verified, and validated according to the company's Design Control process and has been subjected to extensive safety and performance testing as shown in the test results provided in this submission. Verification and Validation testing data demonstrate that the device meets all of its specifications including compliance with the following standards:

ISO 10993-1: 2009-10-15 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process [Including: Technical Corrigendum 1 (2010)]
ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2010 Biological evaluation of medical devices. Tests for irritation and skin sensitization
ANSI AAMI ES60601-1:2005/(R) 2012 and A1:2012 Medical electrical equipment. General requirements for basic safety and essential performance
IEC 60601-1-2:2014 Medical electrical equipment - part 1-2: general requirements for safety - collateral standard: electromagnetic compatibility - requirements and tests

9. Conclusions

The electrical safety, EMC, biocompatibility, software verification and validation, basic unit characteristics, and output specifications information provided is sufficient to demonstrate substantial equivalence to the predicate device. As the Air Compression Therapy System, model: Airpro-690 is nearly identical to the predicate device, differences in their characteristics do not raise any raise new questions regarding safety and effectiveness with identical indications for use and essentially identical technological characteristics, the Air Compression Therapy System, model: Airpro-690 is substantially equivalent to the predicate device Compressible Limb Therapy System, Model LX7(V7).