September 15, 2020

JKH USA, LLC
Bill Dai
Manager
14271 Jeffrey Rd. #246
Irvine, California 92620

Re: K201645
Trade/Device Name: Massage Compression Boots
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: June 14, 2020
Received: June 17, 2020

Dear Dr. Bill Dai:

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

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)*
K201645

Device Name
Massage Compression Boots

Indications for Use *(Describe)*
The Massage Compression Boots are intended for the temporary relief of minor muscle aches and/or pains, and for the temporary increase in circulation to the treated areas. The device can 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.

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510(k) Summary

1. Submitter's Information

Submitter: JKH USA, LLC
Mailing Address: 14271 Jeffrey Rd. #246, Irvine, CA 92620
Contact Person: Dr. Bill Quanqin Dai
Tel: 909-929-9896
Email: Bill@jkhUSA.com
Date of Preparation: 06/14/2020

2. Subject Device

Trade/Device Name: Massage Compression Boots
Common Name: Massager, Powered Inflatable Tube
Regulation Medical Specialty: Physical Medicine
Review Panel: Physical Medicine
Product Code: IRP
Regulation Number: 21 CFR 890.5650
Device Class: II
Use: Over-The-Counter (OTC)

3. Predicate device

Primary Predicate Device: 2004-OC Massage System
510(k) Number: K122112
Clearance Date: April 9, 2013
Submitter: Bio Compression Systems, Inc.

Predicate Device: Compression Therapy Device Model LGT-2200SP
510(k) Number: K191862
Clearance Date: October 29, 2019
Submitter: Guangzhou Longest Science & Technology Co., Ltd.

4. Description of Subject Device

The subject device is a portable and rechargeable device. It is intended to be an over-the-counter portable inflatable tube massage system which simulates kneading and stroking of tissue by use of an inflatable garment. It can be used to temporarily increase blood circulation and temporarily relieve minor muscle aches and pains.

The device, supplied clean and non-sterile, utilizes the pneumatically controlled chambers actuated by an electronically controlled air pump unit. All pump, battery and control components are protectively housed in a plastic case of the control unit that is permanently attached to an inflatable sleeve of multiple air chambers. An ON/OFF button, a SET button, and a display of LEDs provide for user interface. There is also a port for connecting the battery charger/AC adapter plug. The sleeve component consists of multiple air chambers/bladders encased inside a soft medical fabric or equivalent medical material for increased patient comfort and biocompatibility compliance.

In operation, the user simply turns the power on via the ON/OFF button. A sleeve containing the air chambers is connected to the control unit. And the control unit then inflates the sleeve to the pre-determined or adjusted pressure. The sleeve pressure is monitored by an internal pressure switch and system software. Once the sleeve pressure of the air chambers reaches the proper level, the pump is

turned off for a rest period, and the sleeve deflates to the ambient pressure through a valve inside the plastic case. After the rest period, the cycle of inflation and deflation repeats until the unit is turned off.

5. Indications for Use

The Massage Compression Boots are intended for the temporary relief of minor muscle aches and/or pains, and for the temporary increase in circulation to the treated areas. The device can simulate kneading and stroking of tissues by using an inflatable garment.

6. Summary of Substantial Equivalence

The following comparison Table 1 summarizes the comparison between the subject device and the predicate device, indicating the intended use and technical characteristics of the subject device are substantially equivalent to those of the predicate device.

Table 1. Comparison between the subject device and the predicate device

	Subject Device	**Primary Predicate Device**	**Predicate/Reference Device**	**Equivalence**
510(k) Number	N/A	K122112	K191862	N/A
Submitter	JKH USA, LLC	Bio Compression Systems, Inc.	Guangzhou Longest Science & Technology Co., Ltd.	N/A
Device Name/Model	Massage Compression Boots	2004-OC Massage System	Compression Therapy Device Model LGT-2200SP	N/A
Classification Name	Powered Inflatable Tube Massager	Powered Inflatable Tube Massager	Powered Inflatable Tube Massager	Identical
Regulation Class	2	2	2	Identical
Regulation Number	21 CFR 890.5650	21 CFR 890.5650	21 CFR 890.5650	Identical
Principal of Operation	Pneumatic compression	Pneumatic compression	Pneumatic compression	Identical
Intended Use	The Massage Compression Boots are intended for the temporary relief of minor muscle aches and/or pains, and for the temporary increase in circulation to the treated areas. The device can simulate kneading and stroking of tissues by using an inflatable garment.	The 2004-OC Massage Systems are powered inflatable tube massagers intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas. The devices are intended for home use by people who are in good health.	Compression Therapy Device LGT-2200SP is intended for the temporary relief of minor muscle aches and pains and for the temporary increase in circulation to the treated areas, it can simulate kneading and stroking of tissues by using an inflatable garment.	Identical
Prescription or OTC	OTC	OTC	OTC	Identical
Power Source(s)	5-12V DC power supply (100-240 VAC input) and 3.7V rechargeable battery	115 VAC, 50-60 Hz	AC 100-240V, 50/60Hz Battery 11.1V, 6500mAh	Identical or similar. The voltage difference of power supply used does not change the product performance or parameters, which does not raise any new issue of the safety or effectiveness.
Internal rechargeable batteries	Yes	No	Yes	Identical to the Predicate/Reference Device. The battery used or not does not raise any new issue

				of the safety or effectiveness.
Compliance with Voluntary Standards?	Yes	Yes	Yes	Identical
Electrical Safety Mechanical Safety Chemical Safety Thermal Safety Radiation Safety?	Yes	Yes	Yes	Identical
Functions and design	Simulate kneading and stroking of tissue by use of inflatable pressure cuffs	Simulate kneading and stroking of tissue by use of inflatable pressure cuffs	Simulate kneading and stroking of tissue by use of inflatable pressure cuffs	Identical
Target Population / Intended Users	Users who need temporary increase of blood circulation in the treated area and temporary relief of minor muscular aches and pains	Users who need temporary increase of blood circulation in the treated area and temporary relief of minor muscular aches and pains	Users who need temporary increase of blood circulation in the treated area and temporary relief of minor muscular aches and pains	Identical
Intended use Environment	Clinics, hospital, athlete training, and home environments	Clinics, hospital, athlete training, and home environments	Clinics, hospital, athlete training, and home environments	Identical
Application	Non-invasive / external	Non-invasive / external	Non-invasive / external	Identical
Basis of operation	Using cyclic, intermittent, pneumatic pressure application (inflation followed by deflation)	Using cyclic, intermittent, pneumatic pressure application (inflation followed by deflation)	Using cyclic, intermittent, pneumatic pressure application (inflation followed by deflation)	Identical
Anatomical Site / Location of treatment application	Leg, arm/shoulder, and hip/waist	Leg and arm/shoulder	Leg, arm, waist, hip, and thigh	Identical
Software Micro-processor Control	Microprocessor	Microprocessor	Microprocessor	Identical
Pressure Source	Micro pump controlled by microprocessor	Micro pump controlled by microprocessor	Micro pump controlled by microprocessor	Identical
Pressure Range	0-120 mmHg	30-80 mmHg	30-150 mmHg	Identical or similar. The subject device has the compression pressure within the range of the primary predicate device, which does not raise any new issue of the safety or effectiveness.
Cycle Time	60-150 seconds	90 seconds	N/A	Identical or similar. The subject device has the cycle time cover that of the primary predicate device, which does not raise any new issue of the safety or effectiveness.
System diagnostics	Audible and visual alarms prompt recognition of system faults	Visual alarms prompt recognition of system faults	Audible and visual alarms prompt recognition of system faults	Identical
Air delivery from pump to cuff bladder	Via flexible plastic tube(s) connected directly to the air bladder	Via flexible plastic tube(s) connected directly to the air bladder	Via flexible plastic tube(s) connected directly to the air bladder	Identical
Sterility	Clean / non-sterile	Clean / non-sterile	Clean / non-sterile	Identical
Cuff usage	Single Patient Use	Single Patient Use	Single Patient Use	Identical
Material Used	ABS housing and Nylon fabric sleeve	ABS housing and Nylon fabric sleeve	ABS housing and Nylon fabric sleeve	Identical

Biocompatibility	Biocompatible	Biocompatible	Biocompatible	Identical
Patient Contact	Non-conductive appliances	Non-conductive appliances	Non-conductive appliances	Identical
Dimensions	165x83x55mm	305x203x140mm	270x148x129mm	Identical of similar. The difference of dimensions does not raise any new issue of safety or effectiveness
Weight Approx.	0.80kg	3.6kg	2kg	Identical or similar. The difference of weight does not raise any new issue of safety or effectiveness

7. Substantial Equivalence

As shown in the above table of comparison, the subject device in this submission has the identical performance and parameter to the predicate device. And the differences discussed between the subject device and the predicate device do not raise any new issues of safety or effectiveness.

The subject device is substantially equivalent to the predicate devices listed in function and operating principals to achieve identical results. The predicate device utilizes microprocessor controlled pumps to deliver pressurized air to chambers that are attached to the user's body area. Each cycle consists of air inflation of chambers, followed by a rest period during which the chambers deflate and the relax without any compression.

Identical to the predicate device, the subject device has multiple audible and visual safety alarms built into the system, including the low pressure alarm and low battery alarm. In addition, the sleeve is comprised of multiple bladder PVC chambers encased in a covering of soft and non-latex medical fabric or equivalent medical material for increased patient comfort and biocompatibility compliance. The microprocessor and pump units are powered by internal rechargeable batteries, and can be connected to the main AC power line (through the battery charger / AC adaptor) while in use, allowing uninterrupted prolonged service.

The skin contact components and materials of the subject device are identical to those of the predicate device in formulation, suppliers, processing, and geometry and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents, etc.). Therefore, there is no issue or concern of biocompatibility.

As demonstrated, the differences between the subject and predicate devices do not affect the intended use or alter the fundamental technology of the device. There are no new safety or effectiveness issues concerning the subject device, which offers substantially equivalent technical specifications, features, intended use, safety, and effectiveness to the predicate device.

8. Non-Clinical Tests Performed

Non-clinical tests were performed on the subject device in order to validate the design and to assure conformance with the following voluntary design standards in connection with medical device electrical safety, and electromagnetic compatibility.

(a) ANSI AAMI ES60601-1 "Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1)".

(b) IEC 60601-1-2 "Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral standard: Electromagnetic Compatibility - Requirements and Tests".

In addition to the compliance of voluntary standards, bench tests have been performed on the physical requirements, electrical requirement, and performance requirement; the verification of software used in the subject device has been carried out according to the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

9. Conclusion

The tests and comparison performed demonstrate the subject device is substantially equivalent to the predicate device. Therefore, the subject device is as safe and effective as the predicate device that has been legally marketed in the United States.