February 23, 2024

JKH Health Co., Ltd.
% Bill Dai
Managing Member
Jkh Usa LLC
20 Fairbanks, Suite 171
Irvine, California 92618

Re: K240011
Trade/Device Name: Lymphedema Compression
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible limb sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: December 8, 2023
Received: January 2, 2024

Dear 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Eric E. Richardson -S

for Nicole Gillette
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240011

Device Name

Lymphedema Compression

Indications for Use *(Describe)*

The Lymphedema Compression is comprised of a gradient compression sleeve and a portable intermittent pump to provide graduated compression in both sustained and intermittent settings for use in both the hospital and outpatient setting. It is pre-set to the default setting of 50 mmHg that cannot be adjusted or can be adjusted by the physician to a pressure within the specified range. It is intended for use in:

- Treatment of lymphedema
- Treatment of chronic venous insufficiency
- Treatment and promotion of healing of stasis dermatitis and venous stasis ulcers
- Reducing venous leg ulcer healing time
- Reducing edema due to venous stasis
- Enhancing venous return

The device is intended for home, and hospital use.

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

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Date of Preparation: 12/8/2023

2. Subject Device

Trade/Device Name: Lymphedema Compression
Common Name: Compressible Limb Sleeve
Regulation Medical Specialty: Cardiovascular
Review Panel: Cardiovascular
Product Code: JOW
Regulation Number: 21 CFR 870.5800
Device Class: II
Use: Prescription

3. Predicate device

Predicate Device: ManaFlow
510(k) Number: K200353
Clearance Date: August 6, 2020
Submitter: ManaMed, Inc.

4. Description of Subject Device

As a portable and rechargeable prescriptive device, the Lymphedema Compression is intended to be used in the home or clinical/hospital setting by or under the direction of a medical professional. It applies pressure to treat lymphedema and other edematous conditions.

Supplied clean and non-sterile, the Lymphedema Compression utilizes the pneumatically controlled cuff and is 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, which is attached to an inflatable cuff/sleeve. The Lymphedema Compression contains an ON/OFF button, a SET button, and a display for user interface. In addition, there is also a port on the control unit for connecting the battery charger/AC adapter plug. The cuff component consists of multiple air chambers/bladders encased inside a soft nylon fabric or equivalent biocompatible fabric for increased patient comfort and biocompatibility compliance.

In operation, the user simply press the ON/OFF button to turn on the control unit, to which a cuff containing air chambers/bladders is connected. And the control unit then inflates the cuff to the default pre-determined pressure (50 mmHg) that cannot be adjusted or can be adjusted to a pressure within the specified range via the SET button. Once the cuff pressure of the multiple air chambers/bladders reaches the pre-determined or adjusted level, the pump is turned off, and the cuff deflates to the ambient pressure through a valve inside the control unit. After the rest period, the cycle of inflation and deflation repeats until the device is turned off automatically or manually.

5. Indications for Use

Prescription Use:

The Lymphedema Compression is comprised of a gradient compression sleeve and a portable intermittent pump to provide graduated compression in both sustained and intermittent settings for use in both the hospital and outpatient setting. It is pre-set to the default setting of 50 mmHg that cannot be adjusted or can be adjusted by the physician to a pressure within the specified range. It is intended for use in:

- Treatment of lymphedema
- Treatment of chronic venous insufficiency
- Treatment and promotion of healing of stasis dermatitis and venous stasis ulcers
- Reducing venous leg ulcer healing time
- Reducing edema due to venous stasis
- Enhancing venous return

The device is intended for home, and hospital use.

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**	**Equivalence**
510(k) Number	N/A	K200353	N/A
Device Name/Model	Lymphedema Compression	ManaFlow	N/A
Submitter	JKH Health Co., Ltd.	ManaMed, Inc.	N/A
Intended Use	The Lymphedema Compression is comprised of a gradient compression sleeve and a portable intermittent pump to provide graduated compression in both sustained and intermittent settings for use in both the hospital and outpatient setting. It is pre-set to the default setting of 50 mmHg that cannot be adjusted or can be adjusted by the physician to a pressure within the specified range. It is intended for use in: • Treatment of lymphedema • Treatment of chronic venous insufficiency • Treatment and promotion of healing of stasis dermatitis and venous stasis ulcers • Reducing venous leg ulcer healing time • Reducing edema due to venous stasis • Enhancing venous return The device is intended for home, and hospital use.	The ManaFlow system, part numbers MFLOW51 and MFLOW52, is comprised of a gradient compression sleeve and a portable intermittent pump to provide graduated compression in both sustained and intermittent settings for use in both the hospital and outpatient setting. ManaFlow 51 is pre-set to the default setting of 50 mmHg and cannot be adjusted, whereas the ManaFlow 52 can be adjusted by the physician to a pressure within the specified range. It is intended for use in: • Treatment of lymphedema • Treatment of chronic venous insufficiency • Treatment and promotion of healing of stasis dermatitis and venous stasis ulcers • Reducing venous leg ulcer healing time • Reducing edema due to venous stasis • Enhancing venous return	Identical

		The device is intended for home, and hospital use.	
Prescription or OTC	Prescription	Prescription	Identical
Power Source(s)	5V DC power supply (100-240 VAC input) and 3.7V rechargeable battery	5V DC power supply (100-240 VAC input) and 3.7V rechargeable battery	Identical
Battery Charge	Takes approximately 4 hours (from depleted state).	Takes approximately 4 hours (from depleted state).	Identical
Power Supply	Input: 100 - 240 Vac, 50 - 60 Hz, Output: 5 Vdc @ 2 Amp)	Input: 100 - 240 Vac, 50 - 60 Hz, Output: 5 Vdc @ 2 Amp)	Identical
Internal rechargeable batteries	Yes	Yes	Identical
Compliance with Voluntary Standards?	Yes	Yes	Identical
Electrical Safety Mechanical Safety Chemical Safety Thermal Safety Radiation Safety?	Yes	Yes	Identical
Functions and design	Aids venous return by using cyclic, intermittent, pneumatic pressure application (inflation followed by deflation) to compress the extremities.	Aids venous return by using cyclic, intermittent, pneumatic pressure application (inflation followed by deflation) to compress the extremities.	Identical
Contraindication(s)	MUST NOT be used to treat the following conditions: Persons with suspected, active or untreated: deep vein thrombosis, ischemic vascular disease, severe arteriosclerosis, pulmonary edema, severe congestive heart failure, thrombophlebitis, or an active infection. On the legs where cuffs would interfere with the following conditions: vein ligation, gangrene, dermatitis, open wounds, a recent skin graft, massive edema or extreme deformity of the leg. On any neuropathy. On extremities that are insensitive to pain. Where increased venous or lymphatic return is undesirable.	MUST NOT be used to treat the following conditions: Persons with suspected, active or untreated: deep vein thrombosis, ischemic vascular disease, severe arteriosclerosis, pulmonary edema, severe congestive heart failure, thrombophlebitis, or an active infection. On the legs where cuffs would interfere with the following conditions: vein ligation, gangrene, dermatitis, open wounds, a recent skin graft, massive edema or extreme deformity of the leg. On any neuropathy. On extremities that are insensitive to pain. Where increased venous or lymphatic return is undesirable.	Identical
Target Population / Intended Users	Patients who need venous return and lymphedema treatment	Patients who need venous return and lymphedema treatment	Identical
Where Used	Home, Hospital, Surgery Center, Altitude travel, areas of limited mobility	Home, Hospital, Surgery Center, Altitude travel, areas of limited mobility	Identical
Application	Non-invasive / external	Non-invasive / external	Identical
Portability	Portable, ambulant	Portable, ambulant	Identical
Basis of operation	Aids venous return by using cyclic, intermittent, pneumatic pressure application (inflation followed by deflation) to compress the extremities	Aids venous return by using cyclic, intermittent, pneumatic pressure application (inflation followed by deflation) to compress the extremities	Identical
Anatomical Site / Location of treatment application	Extremities	Leg	Identical or Similar
System management	Microprocessor	Microprocessor	Identical
Pressure Source	Micro pump controlled by microprocessor	Micro pump controlled by microprocessor	Identical
Operating Modes	Preset and adjustable modes	Preset and adjustable modes	Identical
Working Pressure	Preset at 50 mmHg and adjustable from 20 – 80 mmHg	Preset at 50 mmHg and adjustable from 20 – 80 mmHg	Identical
Cycle Time	In the preset 50mmHg mode, each chamber will inflate in sequence, starting at the foot and working up toward the knee until all of	In the preset 50mmHg mode, each chamber will inflate in sequence, starting at the foot and working up toward the knee until all of	Identical

	the chambers reach the intended pressure levels. All four chambers will then deflate to the low pressure level. This cycle of inflation and deflation will continue until the device is turn off. In the adjustable 20 - 80 mmHg mode, the pressure of each chamber could be adjusted first, and each chamber will inflate in sequence, starting at the foot and working up toward the knee until all of the chambers reach the intended pressure levels. All the chambers will then deflate to the low pressure level. This cycle of inflation and deflation will continue until the device is turn off.	the chambers reach the intended pressure levels. All four chambers will then deflate to the low pressure level. This cycle of inflation and deflation will continue until the device is turn off. In the adjustable 20 - 80 mmHg mode, the pressure of each chamber could be adjusted first, and each chamber will inflate in sequence, starting at the foot and working up toward the knee until all of the chambers reach the intended pressure levels. All the chambers will then deflate to the low pressure level. This cycle of inflation and deflation will continue until the device is turn off.	
System diagnostics	Audible and 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	Identical
Sterility	Clean / non-sterile	Clean / non-sterile	Identical
Leg cuff usage	Single Patient Use	Single Patient Use	Identical
Material Used	Air bladder chambers encased in a covering of soft and nonlatex medical fabric or equivalent medical material for increased patient comfort and biocompatibility compliance.	Air bladder chambers encased in a covering of soft and nonlatex medical fabric or equivalent medical material for increased patient comfort and biocompatibility compliance.	Identical
Fastening between the plastic case and the fabric wrap	Snap and screw	Snap and screw	Identical
Biocompatibility	Biocompatible	Biocompatible	Identical
Software	Moderate	Moderate	Identical
Temperature	+10 ºC (50 ºF) to +40 ºC (104 ºF)	+10 ºC (50 ºF) to +40 ºC (104 ºF)	Identical
Humidity	30%-75%	30%-75%	Identical
Cleaning and Disinfecting	• Clean the outer surface of the pump unit using a soft cloth, moistened with soapy water or 70% isopropyl alcohol. • Do not use abrasive or volatile cleaners. • Do not place cuffs in dryer. • NEVER remove the unit from the cuff. • Hand wash the exterior of the cuffs using a soft cloth, moistened with soapy water or 70% isopropyl alcohol and let air dry. • To ensure the unit IS completely dry prior to use, leave unit in the OFF condition and disconnected from the wall outlet for 30 minutes after cleaning or disinfecting.	• Clean the outer surface of the pump unit using a soft cloth, moistened with soapy water or 70% isopropyl alcohol. • Do not use abrasive or volatile cleaners. • Do not place cuffs in dryer. • NEVER remove the unit from the cuff. • Hand wash the exterior of the cuffs using a soft cloth, moistened with soapy water or 70% isopropyl alcohol and let air dry. • To ensure the unit IS completely dry prior to use, leave unit in the OFF condition and disconnected from the wall outlet for 30 minutes after cleaning or disinfecting.	Identical
Disposal	This unit is an electromechanical device that includes printed circuit boards and rechargeable batteries. Do not discard in landfill. Consult local county requirements for proper disposal instructions. Pump control units contain rechargeable batteries. Do not discard the pump unit in regular waste. Bring the unit to your local recycle center or contact the seller	This unit is an electromechanical device that includes printed circuit boards and rechargeable batteries. Do not discard in landfill. Consult local county requirements for proper disposal instructions. Pump control units contain rechargeable batteries. Do not discard the pump unit in regular waste. Bring the unit to your local recycle center or contact ManaMed, Inc.	Identical

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 there is no difference between the subject device and the predicate device, and there is no new issue of safety or effectiveness. The subject device is designed for the same intended use as the predicated device. The comparison of the specifications demonstrates the functional equivalence of the products, concluding that the subject device is substantially equivalent to the predicate device.

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 bladders that are attached to the patient's extremities. Each cycle consists of inflation of air bladders, followed by the bladder deflation and relaxation without any compression.

Identical to the predicate device, the subject device has multiple audible and visual safety alarms built into the system, including low pressure alarm and low battery alarm. 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. In addition, the cuff is comprised of multiple air bladder chambers encased in a covering of soft and non-latex nylon fabric or equivalent biocompatible fabric for increased patient comfort and biocompatibility compliance. 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.

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. Clinical Testing

Clinical testing was not needed in support of this 510(k) application.

10. 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.