May 26, 2021

ManaMed, Inc.
% Bill Quanqin Dai, Ph.D.
JKH USA, LLC
14271 Jeffrey Rd. #246
Irvine, California 92620

Re: K211253
Trade/Device Name: PlasmaWave
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: April 14, 2021
Received: April 26, 2021

Dear Dr. 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,

Nicole Gillette
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211253

Device Name
PlasmaWave

Indications for Use *(Describe)*
The PlasmaWave is intended to be an easy to use portable system, prescribed by a physician, for use in the home or clinical setting to help prevent the onset of DVT in patients by stimulating blood flow in the extremities (stimulating muscle contractions). This device can be used to:

- Aid in the prevention of DVT;
- Enhance blood circulation;
- Diminish post-operative pain and swelling;
- Reduce wound healing time;
- Aid in the treatment and healing of stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency and reduction of edema in the lower limbs.

The unit can also be used as an aid in the prophylaxis for DVT by persons expecting to be stationary for long periods of time.

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
Submitter: ManaMed, Inc.
Address: 5240 W. Charleston Blvd.
Las Vegas, NV 89146
Date of Preparation: 04/16/2021

2. Subject Device
Trade/Device Name: PlasmaWave
Regulation Description: 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
Primary Predicate Device: PlasmaFlow
510(k) Number: K160318
Clearance Date: April 1, 2016
Submitter: ManaMed, Inc.

Predicate Device: Cirona 6200 Deep Vein Thrombosis Prevention System
510(k) Number: K141578
Clearance Date: June 27, 2014
Submitter: Devon Medical, Inc.

4. Description of Subject Device
The PlasmaWave is a lightweight, portable, rechargeable battery powered prescriptive device. It is intended to be used in the home or clinical setting by or under the direction of a medical professional to help stimulate blood flow as an aid in the prevention of deep vein thrombosis (DVT).

The PlasmaWave utilizes pneumatically controlled, single-chamber wraps actuated by an electronically controlled unit of the air pump and solenoid valve via the tubing. All pump, battery and control components are protectively housed in a plastic case that is connected to a single use inflatable wrap via tubing. A Power On/Off button, a Mode (M) button, a Leg button, three LED indicators (Working, Charging, and Warming), and a LCD display provide user interface. There are also two tubing ports for connecting the tubing and a charging port for connecting the battery charger/AC adapter at the bottom of the control unit.

5. Indications for Use

Prescription Use:

The PlasmaWave is intended to be an easy to use portable system, prescribed by a physician, for use in the home or clinical setting to help prevent the onset of DVT in patients by stimulating blood flow in the extremities (stimulating muscle contractions). This device can be used to:

- Aid in the prevention of DVT;
- Enhance blood circulation;
- Diminish post-operative pain and swelling;
- Reduce wound healing time;
- Aid in the treatment and healing of stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency and reduction of edema in the lower limbs.

The unit can also be used as an aid in the prophylaxis for DVT by persons expecting to be stationary for long periods of time.

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 Device**	**Equivalence**
510(k) Number	N/A	K160318	K141578	N/A
Submitter	ManaMed, Inc.	ManaMed, Inc.	Devon Medical, Inc.	N/A
Device Name/Model	PlasmaWave	PlasmaFlow	Cirona 6200 Deep Vein Thrombosis Prevention System	N/A
Intended Use	The PlasmaWave is intended to be an easy to use portable system, prescribed by a physician, for use in the home or clinical setting to help prevent the onset of DVT in patients by stimulating blood flow in the extremities (stimulating muscle contractions). This device can be used to: • Aid in the prevention of DVT; • Enhance blood circulation; • Diminish post-operative pain and swelling; • Reduce wound healing time; • Aid in the treatment and healing of stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency and reduction of edema in the lower limbs. The unit can also be used as an aid in the prophylaxis for DVT by persons expecting to be stationary for long periods of time.	The PlasmaFlow, model PF0001, is intended to be an easy to use portable system, prescribed by a physician, for use in the home or clinical setting to help prevent the onset of DVT in patients by stimulating blood flow in the extremities (simulating muscle contractions). This device can be used to: • Aid in the prevention of DVT; • Enhance blood circulation; • Diminish post-operative pain and swelling; • Reduce wound healing time; • Aid in the treatment and healing of: stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency and reduction of edema in the lower limbs. The unit can also be used as an aid in the prophylaxis for DVT by persons expecting to be stationary for long periods of time.	The Cirona 6200 Series system is a prescription device intended to be used preventatively to increase venous blood flow in patients at risk of deep vein thrombosis due to the associated risk factors for thrombus formation during: trauma, critical care, general medicine, general surgery, as well as neurological, orthopedic, urologic, obstetric conditions and treatments.	Identical
Prescription or OTC	Prescription	Prescription	Prescription	Identical

Power Source(s)	Rechargeable battery	Rechargeable battery	Rechargeable battery	Identical
Battery Specifications	3.7V rechargeable battery	3.7V rechargeable battery	10.8V rechargeable battery	Identical or similar. The voltage difference of batteries will not raise any new issue of the safety or effectiveness.
Battery Charge	Takes approximately 4 hours (from depleted state).	Takes approximately 4 hours (from depleted state).	Takes approximately 5 hours (from depleted state).	Identical or similar. The difference of charging time does not change the product performance or parameters, which will not raise any new issue of the safety or effectiveness.
Power Supply	Input: 100 - 240 Vac, 50 - 60 Hz, Output: 12 Vdc @ 2 A	Input: 100 - 240 Vac, 50 - 60 Hz, Output: 5 Vdc @ 1 A	Input: 100 - 240 Vac, 50 - 60 Hz, Output: 14 Vdc @ 2 A	Similar. The voltage difference of power supply used does not change the product performance or parameters, which will not raise any new issue of the safety or effectiveness.
Internal rechargeable batteries	Yes	Yes	Yes	Identical
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	Aids venous return by using cyclic, intermittent, pneumatic pressure application (inflation followed by deflation) to compress the lower extremities.	Aids venous return by using cyclic, intermittent, pneumatic pressure application (inflation followed by deflation) to compress the lower extremities.	Aids venous return by using cyclic, intermittent, pneumatic pressure application (inflation followed by deflation) to compress the lower extremities	Identical
Contraindication(s)	The PlasmaFlow 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.	The PlasmaFlow 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.	The Cirona 6200 Series system should NOT be used in the following conditions: • Severe atherosclerosis or other ischemic vascular diseases • Suspected or known acute deep vein thrombosis • Severe congestive cardiac failure • Existing pulmonary edema • Existing pulmonary embolisms • Extreme deformity of the limbs • Any local skin or tissue condition in which the garments would interfere: • Gangrene • Untreated or infected wounds • Recent skin graft • Dermatitis • Known presence of malignancy in the legs	Identical

			• Limb infections, including cellulitis, that have not received antibiotic coverage • Presence of lymphangiosarcoma	
Target Population / Intended Users	Patients who need venous return.	Patients who need venous return.	Patients who need venous return.	Identical
Where Used	Home, Hospital, Surgery Center, Altitude travel, areas of limited mobility	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	Non-invasive / external	Identical
Portability	Portable, ambulant	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 lower extremities.	Aids venous return by using cyclic, intermittent, pneumatic pressure application (inflation followed by deflation) to compress the lower extremities.	Aids venous return by using cyclic, intermittent, pneumatic pressure application (inflation followed by deflation) to compress the lower extremities.	Identical
Anatomical Site / Location of treatment application	Lower extremities	Lower extremities	Lower extremities	Identical
System management	Electronic, microprocessor controlled	Electronic, microprocessor controlled	Electronic, microprocessor controlled	Identical
Pressure Source	Micro pump controlled by electronic processor	Micro pump controlled by electronic processor	Micro pump controlled by electronic processor	Identical
Operating Mode	Continuous Operation	Continuous Operation	Continuous Operation	Identical
Working Pressure	Preset at 55 mmHg	Preset at 55 mmHg	Preset at 40 mmHg	Identical or similar. The working pressure of the subject device is identical to that of the primary predicate device, and similar to that of the predicate device. Therefore, it will not raise any new issue of the safety or effectiveness.
Cycle Time	Approximately 60 seconds	Approximately 60 seconds	Approximately 60 seconds	Identical
System diagnostics	Audible and visual alarms prompt recognition of system faults	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 to the air bladder.	Via flexible plastic tube(s) connected to the air bladder.	Via flexible plastic tube(s) connected to the air bladder.	Identical
Sterility	Clean / non-sterile	Clean / non-sterile	Clean / non-sterile	Identical
Leg cuff usage	Single Patient Use	Single Patient Use	Single Patient Use	Identical
Material Used	A single air bladder encased in a covering of soft, nonlatex, non-woven medical fabric or equivalent medical material for increased patient comfort and biocompatibility compliance.	A single air bladder encased in a covering of soft, nonlatex, non-woven medical fabric or equivalent medical material for increased patient comfort and biocompatibility compliance.	A single air bladder encased in a covering of soft, nonlatex, non-woven medical fabric or equivalent medical material for increased patient comfort and biocompatibility compliance.	Identical
Biocompatibility	Biocompatible	Biocompatible	Biocompatible	Identical
Software	Moderate	Moderate	Moderate	Identical
Dimensions	220x70x48.5 mm	116x65x19 mm	110x180x270 mm	Different. The difference of dimensions does not

				change the product performance or parameters, which will not raise any new issue of the safety or effectiveness.
Weight Approx.	0.38kg	0.23kg	2.3kg	Different. The difference of weight does not change the product performance or parameters, which will not raise any new issue of the safety or effectiveness.
Temperature	+10 ºC (50 ºF) to +40 ºC (104 ºF)	+10 ºC (50 ºF) to +40 ºC (104 ºF)	+5 ºC (41 ºF) to +40 ºC (104 ºF)	Identical or similar
Humidity	30%-75%	30%-75%	15%-93%	Identical or similar

7. Substantial Equivalence

As shown in the above table of comparison, the subject device in this submission has the identical or similar performance and parameter to the predicate device. And the differences 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 bladders that are attached to the patient's lower extremities, using a cycle time of approximately 60 seconds. Each cycle consists of inflation of a bladder, followed by a rest period during which the bladder deflates and the lower extremity relaxes without any compression.

Identical to the predicate device, the subject device has multiple audible and visual alarms built into the system, including low pressure alarms and low battery alarm. In addition, the inflatable wrap (cuff) is comprised of a single air bladder encased in a covering of soft, non-latex, non-woven medical fabric or equivalent medical material for increased patient comfort and biocompatibility compliance. The microprocessor and pump units are powered by an internal rechargeable battery, and can be connected to the main AC power adapter/charger 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.

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.

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 the 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.