August 5, 2020

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

Re: K200351
Trade/Device Name: PlasmaFlight
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: April 29, 2020
Received: May 7, 2020

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,

Amber Ballard, PhD
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200351

Device Name
PlasmaFlight

Indications for Use *(Describe)*
The PlasmaFlight is intended to be an over-the-counter portable inflatable tube massage system which simulates kneading and stroking of tissue with the hands by use of inflatable pressure cuffs. This device can be used to:

- Temporarily increase blood circulation in the treated areas;
- Temporary relief of minor muscle aches and pains.

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: ManaMed, Inc.
Address: 5240 W. Charleston Blvd.
Las Vegas, NV 89146
Contact Person: Trevor Theriot
Tel : 702-781-1117
Date of Preparation: 12/20/2019

2. Subject Device

Trade/Device Name: PlasmaFlight
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

3. Predicate device

Primary Predicate Device: PowerPlay Muscle Massager, PPRT-01
510(k) Number: K122154
Clearance Date: November 21, 2012
Submitter: Fig, LLC

Predicate/Reference Device: PlasmaFlow
510(k) Number: K160318
Clearance Date: April 1, 2016
Submitter: ManaMed, Inc.

4. Description of Subject Device

The PlasmaFlight 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 with the hands by use of inflatable pressure cuffs. It can be used to temporarily increase blood circulation and temporarily relieve minor muscle aches and pains.

The PlasmaFlight, supplied clean and non-sterile, utilizes the pneumatically controlled air bladder cuff 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 cuff. An ON/OFF button and LED indicators/displays provide for user interface. There is also a port for connecting the battery charger/AC adapter plug. The cuff component consists of an air bladder 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 cuff containing the air bladder is permanently connected to the control unit. And the control unit then inflates the cuff to the default pre-determined pressure (55 mmHg). The cuff pressure is monitored by an internal pressure switch and system software. Once the cuff pressure of the air bladder reaches the proper level, the pump is turned

off for a rest period, and the cuff 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 PlasmaFlight is intended to be an over-the-counter portable inflatable tube massage system which simulates kneading and stroking of tissue with the hands by use of inflatable pressure cuffs. This device can be used to:

- Temporarily increase blood circulation in the treated areas;
- Temporary relief of minor muscle aches and pains.

6. Summary of Substantial Equivalence

Identical to that of the primary predicate device, the operational principle of the subject device is to simulate kneading and stroking of tissue by using cyclic, intermittent, pneumatic pressure application (inflation followed by deflation) to compress the extremities. The primary predicate device and the subject device have the same Indications for Use, and both of them are for the Over-The-Counter use.

In addition, the subject device PlasmaFlight was originally named PlasmaFlow in the predicate/reference K160318. PlasmaFlight and PlasmaFlow are the same except the Indications for Use. Therefore, K160318 is listed as the predicate device for reference.

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	K200351	K122154	K160318	N/A
Submitter	ManaMed, Inc.	Fig, LLC	ManaMed, Inc.	N/A
Device Name/Model	PlasmaFlight	PowerPlay Muscle Massager, PPRT-01	PlasmaFlow	N/A
Intended Use	The PlasmaFlight is intended to be an over-the-counter portable inflatable tube massage system which simulates kneading and stroking of tissue with the hands by use of inflatable pressure cuffs. This device can be used to: • Temporarily increase blood circulation in the treated areas; • Temporary relief of minor muscle aches and pains.	The PowerPlay model PPRT-01 is intended to be an over-the-counter portable inflatable tube massage system which simulates kneading and stroking of tissue with the hands by use of inflatable pressure cuffs. This device can be used to: • Temporarily increase blood circulation in the treated areas; • Temporary relief of minor muscle aches and pains.	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,	Identical to the Primary Predicate Device

			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.	
Prescription or OTC	OTC	OTC	Prescription	Identical to the primary predicate device
Power Source(s)	5V DC power supply (100-240 VAC input) and 3.7V rechargeable battery	Not publicly available	5V DC power supply (100-240 VAC input) and 3.7V rechargeable battery	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.
Battery Charge	Takes approximately 2-5 hours (from depleted state).	Not publicly available	Takes approximately 4-5 hours (from depleted state).	Identical or similar. The difference of charging time does not change the product performance or parameters, which does not raise any new issue of the safety or effectiveness.
Power Supply	Input: 100 - 240 Vac, 50 - 60 Hz, Output: 5 Vdc @ 1 Amp)	Not publicly available	Input: 100 - 240 Vac, 50 - 60 Hz, Output: 5 Vdc @ 1 Amp)	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	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	Simulates kneading and stroking of tissue with the hands by use of inflatable pressure cuffs	Simulates kneading and stroking of tissue with the hands by use of inflatable pressure cuffs	Aids venous return by using cyclic, intermittent, pneumatic pressure application (inflation followed by deflation) to compress the extremities.	Identical to the primary predicate device
Contraindication (s)	The PlasmaFlight 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	The PowerPlay PPRT-01 must not be used by persons with the following conditions: • Suspected, active or untreated: Neuropathy, deep vein thrombosis, ischemic vascular disease, severe arteriosclerosis, pulmonary edema, congestive	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	Identical

	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.	heart failure, thrombophlebitis or an active infection; • On a leg where wraps 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 extremities that are insensitive to pain; • Where increased circulation is undesirable;	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.	
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	Patients who need venous return	Identical to the primary predicate device
Where Used	Home, Altitude travel, areas of limited mobility	Home, Altitude travel, areas of limited mobility	Home, Hospital, Surgery Center, Altitude travel, areas of limited mobility	Identical to the primary predicate device
Application	Non-invasive / external	Non-invasive / external	Non-invasive / external	Identical
Portability	Portable, ambulant	Portable, ambulant	Portable, ambulant	Identical
Basis of operation	Using cyclic, intermittent, pneumatic pressure application (inflation followed by deflation) to compress the extremities	Using cyclic, intermittent, pneumatic pressure application (inflation followed by deflation) to compress the extremities	Using cyclic, intermittent, pneumatic pressure application (inflation followed by deflation) to compress the extremities	Identical
Anatomical Site / Location of treatment application	Lower limb(s) (Calf)	Calf, ankle, knee, hip or shoulder	Lower limb(s) (Calf)	Identical on the calf
System management	Microprocessor	Microprocessor	Microprocessor	Identical
Pressure Source	Micro pump controlled by microprocessor	Micro pump controlled by microprocessor	Micro pump controlled by microprocessor	Identical
Operating Modes	Two preset modes of 55mmHg	Not publicly available	Two preset modes of 55mmHg	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.
Working Pressure	Preset at approximately 55 mmHg	Adjusted at 30 - 70 mmHg	Preset at approximately 55 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	The PlasmaFlight utilizes microprocessor controlled pumps to deliver approximately 55 mmHg of pressurized air to bladders that are attached to the user's lower limbs, using a cycle time of approximately 60	The PowerPlay utilizes microprocessor controlled pumps to deliver approximately 30 - 70 mmHg of pressurized air to bladders that are attached to the user's lower limbs, using a cycle time of approximately 30 - 60	The PlasmaFlow utilizes microprocessor controlled pumps to deliver approximately 55 mmHg of pressurized air to bladders that are attached to the patient's lower limbs, using a cycle time of approximately 60	Identical or similar. The subject device has the cycle time within the range of the primary predicate device, which does not raise any new issue of

	seconds / leg. Each cycle consists of inflation of a bladder, followed by a rest period during which the bladder deflates and the limb relaxes without any compression.	seconds / leg. Each cycle consists of inflation of a bladder, followed by a rest period during which the bladder deflates and the limb relaxes without any compression.	seconds / leg. Each cycle consists of inflation of a bladder, followed by a rest period during which the bladder deflates and the limb relaxes without any compression.	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
Leg cuff usage	Single Patient Use	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.	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 or similar
Fastening between the plastic case and the fabric wrap	Snap and screw	Snap and tubing	Snap and screw	Identical or similar
Biocompatibility	Biocompatible	Biocompatible	Biocompatible	Identical
Software	Moderate	Moderate	Moderate	Identical
Dimensions	116x65x19mm	Not publicly available	116x65x19mm	Identical of similar. The difference of dimensions does not raise any new issue of safety or effectiveness
Weight Approx.	0.23kg	Not publicly available	0.23kg	Identical or similar. The difference of weight does not raise any new issue of safety or effectiveness
Temperature	+10 ºC (50 ºF) to +40 ºC (104 ºF)	Not publicly available	+10 ºC (50 ºF) to +40 ºC (104 ºF)	Identical
Humidity	30%-75%	Not publicly available	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.	Not publicly available	• 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 or similar

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 ManaMed, Inc.	Not publicly available	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 or similar

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 minor 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 approximately 55 mmHg of pressurized air to the air bladder that is attached to the user's lower extremities. Each cycle consists of inflation of the air bladder, followed by a rest period during which the bladder deflates and relaxes 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 alarms, low battery alarm and system malfunction overpressure safety alarm. In addition, the cuff is comprised of an air bladder 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 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 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.