DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 1, 2016

ManaMed, Inc
% Dave Yungvirt
CEO
Third Party Review Group, LLC
The Old Station House
24 Lackawanna Place
Millburn, NJ 07041

Re: K160318
Trade/Device Name: PlasmaFlow
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: March 17, 2016
Received: March 21, 2016

Dear Dave Yungvirt:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Fernando Aguel -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K160318

Device Name
PlasmaFlow

Indications for Use *(Describe)*
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.

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

## GENERAL INFORMATION

**Applicant:**

510(k) Notification: ManaMed, Inc.
287 Cabrillo St. Unit C
Costa Mesa, CA 92627
U.S.A.
Phone: 949-632-0355
Fax: 949-258-9900

**Contact Person:**

Trevor Theriot
President
287 Cabrillo St. Unit C
Costa Mesa, CA 92627
U.S.A.
Phone: 949-632-0355
Fax: 949-258-9900

**Date Prepared:**

March 29, 2016

## DEVICE INFORMATION:

The PlasmaFlow is an ambulatory, portable, light weight, prescriptive intermittent pneumatic compression system intended to provide sequential compression therapy to a patient's lower limbs. All pump control unit components are protectively enclosed in a plastic casing which is fixated to a single chamber cuff. The unit is supplied with a non-serviceable, rechargeable battery, to allow user portability, and a power supply transformer for main connection.

**Trade Name / Model:**

PlasmaFlow / PF0001

**Generic/Common Name:**

Compressible Limb Sleeve Device

**Classification:**

Compressible Limb Sleeve, 21 CFR 870.5800
Class: II

**Product Code:**

JOW

## PREDICATE DEVICE

Innovamed Health, *VENAPRO* (**K133274**)

Reference Device Information: Cothera, *VPULSE* (K122640)

**Intended Use and Indications for Use of the subject device:**

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.

**Contraindications:**

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 a leg 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 patients with neuropathy; On extremities that are insensitive to pain; Where increased venous or lymphatic return is undesirable.

**PRODUCT DESCRIPTION:**

The PlasmaFlow is an ambulatory, portable, light weight, prescriptive device intermittent pneumatic compression system intended to provide sequential compression therapy to a patient's lower limbs. The housing on the garment is a lightweight, rechargeable battery-powered, electromechanical control unit intended to provide and digitally monitor through two LED screens the inflation cycle for enhanced circulation therapy. The controller on the sleeve allows the unit to inflate distal to proximal. It is intended to be used in the home, travel situations where altitude or lack of mobility occurs, 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).

All pump control unit components are protectively enclosed in a plastic casing which is fixated to a single chamber cuff. The unit is supplied with a non-serviceable, rechargeable battery, to allow user portability, and a power supply transformer for main connection. The pump has two LED screens. The screen allows the prescriber and or patient to verify the pressure, the mode, and total run time.

The Patient Sleeve is a single Polyvinyl Chloride (PVC) air bladder intended to be

attached directly to the patient's lower limb. It is intended to provide compression action to the tissue surrounding the venous vasculature in the calf of a patient. A compression unit with two LED screens is connected to sleeve for a completely ambulatory system. The compression unit has the ability to produce different compression modalities.

Default modality will be the same as the predicated devices, which is, a slow inflation up to 55 mmHg of air through the bladder cells. Once pressure is reached, the unit will deflate for approximately 50 seconds. Then the cycle repeats.

Another compression modality will be the step up technology that inflates the air cells at an increase of 10 mmHg pausing at increments of ten to 50 mmHg, with a final increase of 5 mmHg to 55mmHg. Once 55 mmHg is reached, the unit will decrease to 50 mmHg and then decrease in increments of 10 mmHg.

A single touch control switch located on the top of the unit powers on the unit and switches the mode.

Above the power button, a dual color LED light allows the user to verify for power on, low battery, charging and charge completed indication, and an audible alarm (for indicating a leak or low pressure alarm) provides for user interface. There is also a port for connecting the battery charger/AC adapter plug/USB chord.

The leg wrap (cuff) component consists of a Polyvinyl Chloride (PVC) air bladder encased inside a soft, non-woven medical fabric made from a Polyester blended medical fabric or equal, which is adhered to the PVC air bladder. The units are supplied clean, non-sterile, packaged in pairs.

In operation, the user simply runs the power ON via the multi-purpose control button. A single user "cuff' containing air bladders is connected to the unit. The control unit then fills the cuff to a pressure of 55 mmHg. Cuff pressure is visually monitored by user pressure LED screen, internal pressure switch, and system software. Once the pressure reaches the proper level, the pump is deflated for an approximately 50 second deflate period. The device software ensures the cycle time is a minimum of 60 seconds (the cycle time is the length of time for one complete cycle on one cuff including fill time, exhaust, and relaxation time). The cycle repeats until the unit is turned off.

## SUBSTANTIAL EQUIVALENCE:

The intended for use for the PlasmaFlow are substantially equivalent to the proposed indications for use for the predicate device. Any differences in the technological characteristics between the devices do not raise any new issues of safety or effectiveness. Thus, the PlasmaFlow is substantially equivalent to the predicate device. A comparison of the main characteristics and features of these devices is provided as a table formant and detailed discussion.

| Characteristics / Features | **PlasmaFlow Subject Device** | **Venapro Predicate (K133274)** | **Comments** |
|---|---|---|---|
| COMPARISON OF GENERAL INFORMATION / USES AND INDICATIONS | | | |
| Photograph |  |  | For Information Purposes only |
| FDA Device Description | Compressible Limb Sleeve, 21 CFR 870.5800 | Compressible Limb Sleeve, 21 CFR 870.5800 | Identical; therefore substantially equivalent. |
| FDA Product Code | JOW | JOW | Identical; therefore substantially equivalent. |
| Function | Aids venous return by using cyclic, intermittent, pneumatic pressure application (inflation followed by deflation) to compress the lower limb(s). | Aids venous return by using cyclic, intermittent, pneumatic pressure application (inflation followed by deflation) to compress the lower limb(s). | |
| Indications for use | 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:<br><br>• Aid in the prevention of DVT;<br>• Enhance blood circulation;<br>• Diminish post-operative pain and swelling;<br>• Reduce wound healing time;<br>• Aid in the treatment and healing of: stasis dermatitis, venous stasis | •The Vena Pro Vascular Therapy System, model VP-31 II, 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:<br><br>* Aid in the prevention of DVT;<br>* Enhance blood circulation;<br>* Diminish post-operative pain and swelling;<br>* Reduce wound healing time;<br>* Aid in the treatment and healing of: stasis dermatitis, venous stasis | Identical except for branding issues; therefore substantially equivalent. |

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| | ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency and reduction of edema in the lower limbs.<br><br>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. | ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency and reduction of edema in the lower limbs.<br><br>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. | |
| 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 a leg 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 patients with neuropathy; On extremities that are insensitive to pain; Where increased venous or lymphatic return is undesirable. | The VenaPro 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; therefore substantially equivalent. |
| Target Population / Intended Users | Patients who need venous return. | Patients who need venous return. | Identical; therefore substantially equivalent. |
| Where Used | Home, Hospital, Surgery Center, | Home, Hospital, Surgery Center, | Identical; therefore substantially equivalent. |

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| | Altitude travel, areas of limited mobility | Altitude travel, areas of limited mobility | substantially equivalent. |
| Application | Non-invasive / external | Non-invasive / external | Identical; therefore substantially equivalent. |
| Portability | Portable, ambulant | Portable, ambulant | Identical; therefore substantially equivalent. |
| Basis of operation | Aids venous return by using cyclic, intermittent, pneumatic pressure application (inflation followed by deflation) to compress the lower limb(s). | Aids venous return by using cyclic, intermittent, pneumatic pressure application (inflation followed by deflation) to compress the lower limb(s). | Identical; therefore substantially equivalent. |
| Anatomical Site / Location of treatment application | Lower limb(s) (Calf) | Lower limb(s) (Calf) | Identical; therefore substantially equivalent. |
| System management | Electronic, microprocessor controlled | Electronic, microprocessor controlled | Identical; except for different microprocessor design; therefore substantially equivalent. |
| Pressure Source | Micro pump controlled by electronic processor | Micro pump controlled by electronic processor | Identical; except for different pump design; therefore substantially equivalent. |
| Operating Modes | Mode 1<br>Mode 2 | Default mode one | Identical; except for multiple modes; therefore substantially equivalent. Reference device *VPULSE* (K122640) has multiple modes of compression and supports multiple modes used in PlasmaFlow. |

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| Working Pressure | Mode one and Mode two are preset at 55 mmHg | Default mode is preset at 50 mmHg | Identical to the predicate except that PlasmaFlow reaches max pressure of 55mmHg. Reference device *VPULSE* (K122640) supports higher pressure and claims 60 mmHg of pressure. Therefore Substantially Equivalent |
| Cycle Time | 60 seconds | 60 seconds | Identical to the predicate. Therefore Substantially Equivalent |
| System diagnostics | Audible and visual alarms prompt recognition of system faults | Audible and visual alarms prompt recognition of system faults | Identical to the predicate. Therefore Substantially Equivalent |
| Modes | 2 different modes | 1 Modality | Identical; except for multiple modes; therefore substantially equivalent. |
| Battery Specifications | 7.4 volt Li-ion battery pack rechargeable | 7.4 volt Li-ion battery pack rechargeable | Identical; therefore substantially equivalent. |
| Internal rechargeable batteries | Yes | Yes | Identical; therefore substantially equivalent. |
| Air delivery from pump to cuff bladder | Via flexible plastic (PVC) tube(s) connected directly to the air bladder. | Via flexible plastic (PVC) tube(s) connected directly to the air bladder. | Identical; therefore substantially equivalent. |
| Sterility | Clean / non-sterile | Clean / non-sterile | Identical; therefore substantially equivalent. |
| Leg cuff usage | Single Patient Use | Single Patient Use | Identical; therefore substantially equivalent. |
| Material Used | Single bladder PVC chambers encased in a covering of soft, non-latex, non-woven medical fabric (a Polyester blend) or equivalent medical material for increased patient comfort and | Single bladder PVC chambers encased in a covering of soft, non-latex, non-woven medical fabric (a Polyester blend) or equivalent medical material for increased patient comfort and | Identical; except for fabric thickness, color, and feel is different; does not pose a risk in safety or effectiveness as it passed current |

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| | biocompatibility compliance. Grey colored, stitched, and thick. Material does not raise any question of safety or effectiveness. | biocompatibility compliance. White colored, glued, and thin. | testing standards; therefore substantially equivalent. |
| Comparison of Applicable Standards | | | |
| Biocompatibility | Equivalent to predicate confirming with outside testing results. | Passed or N/A | Identical; except for testing results and facilities not available for predicate but standards for device are similar and it is determined predicate had same testing standards; therefore substantially equivalent. |
| Software | Moderate | N/A | Identical; except for testing results and facilities not available for predicate but standards for device are similar and it is determined predicate had same testing standards; therefore substantially equivalent. |
| Standards Met | Equivalent to predicate confirming with outside testing results. | Passed or N/A | Identical; except for testing results and facilities not available for predicate but standards for device are similar and it is |

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| | | | determined predicate had same testing standards; therefore substantially equivalent. |
| Electrical Safety<br>Mechanical Safety<br>Chemical Safety<br>Thermal Safety<br>Radiation Safety | Equivalent to predicate confirming with outside testing results. Safety also confirmed in our risk assessment and usability document. | Passed or N/A | Identical; except for testing results and facilities not available for predicate but standards for device are similar and it is determined predicate had same testing standards; therefore substantially equivalent. |
| Labeling, Packaging, and sterilization Standards | Substantial Equivalent | Substantial Equivalent | Identical; except for design of documents and word choice; does not pose a danger to device safety or effectiveness; therefore substantially equivalent. |
| Technical Data | | | |
| Dimensions | 23" x 10.25" x 1.5" (58cm x 26cm x 4cm) | N/A | Identical to the predicate except that PlasmaFlow measurements pertain to the unit and the sleeve; whereas, Venapro measured only the main unit. Therefore Substantially Equivalent |
| Weight: Approx. | 1.43 lb (.65 kg) | 0.5 lb (0.227 kg) | Identical to the |

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| | | | predicate except that PlasmaFlow weight pertains to both units and the sleeves; whereas, Venapro weighed only the main unit, weights are similar. Therefore Substantially Equivalent |
| Source of Power | DC 8.4V or Inner Battery (7.4 volt Li-ion battery pack—made up of 2 x 3.7 volt cells) | 7.4 volt Li-ion battery pack (made up of 2 – 3.7 volt cells) | Identical to the predicate. Therefore Substantially Equivalent |
| Power Supply | Class II, input: 100 - 240 Vac, 50 - 60 Hz, output: 8.4V @ 1 Amp) | Class II, input: 100 - 240 Vac, 50 - 60 Hz, output: 10 Vdc @ 1.1 Amp) | Identical to the predicate. Therefore Substantially Equivalent |
| Temperature | +10°C (50°F) to +40°C (104°F) | +10 Degrees C (50 Degrees F) to +40 degrees C (104 degrees F) | Identical to the predicate. Therefore Substantially Equivalent |
| Humidity | 30%-75%. Keep dry. | 30%-75% | Identical to the predicate. Therefore Substantially Equivalent |
| Tolerances | 5% | Pressure 5% | Identical to the predicate. Therefore Substantially Equivalent |
| Battery Charge | Approximately 4-5 hours | Takes approximately 6 hours (from depleted state). | Identical to the predicate except that PlasmaFlow claims full charge battery between 4-5 hours. Therefore Substantially Equivalent |
| Cleaning and Disinfecting | | | |

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| Cleaning and Disinfecting | • Clean the outer surface of the pump unit using a soft cloth, moistened with soapy water or 70% isopropyl alcohol. Air dry only.<br>Clean the exterior of the cuffs using a soft cloth, moistened with soapy water or 70% isopropyl alcohol. Air dry.<br>Unit must be completely dry prior to use. To ensure that, leave the device in the OFF position and disconnected from the wall outlet for at least 30 minutes (and as long as necessary for the unit to dry completely) after cleaning or disinfecting.<br>Do not remove the pump unit from the cuff..<br>Do not place cuffs in dryer or microwave.<br>Do not use hair dryer to accelerate drying.<br>Do not place the device on top or in front of portable stationary radiators to accelerate drying.<br>Do not use abrasive cleaners. | • Clean the outer surface of the pump unit using a soft cloth, moistened with soapy water or 70% isopropyl alcohol.<br>• Do not use abrasive or volatile cleaners.<br>• Do not place cuffs in dryer.<br>• NEVER remove the unit from the cuff.<br>• Hand wash the exterior of the cuffs using a soft cloth, moistened with soapy water or 70% isopropyl alcohol and let air dry.<br>• 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 to the predicate except word choice and order; therefore Substantially Equivalent |
| Disposal | | | |
| Disposal | This unit is an electromechanical device that includes printed circuit boards and rechargeable | This unit is an electromechanical device that includes printed circuit boards and rechargeable | Identical to the predicate. Therefore Substantially Equivalent |

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| | 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. | 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 InnovaMed Health. | |

The PlasmaFlow is substantially equivalent to the predicate devices listed in function and operating principals to achieve identical results. The predicate system *(VENAPRO-K133274)* utilize microprocessor controlled pumps to deliver approximately 50 mmHg of pressurized air to bladders that are attached to the patient's lower limbs, using a cycle time of approximately 60 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.

Multiple audible and visual safety alarms are built into the system, similar to those built into the *Venapro,* including; Low pressure alarms, low battery alarm and system malfunction overpressure safety alarm.

Cycle and maximum fill times are available in 2 different modes. The default settings are similar to predicate devices in fill time, cycle time and pressure settings. The default pressure setting for the wraps are factory preset at approximately 55 mmHg and cannot be adjusted.

The PlasmaFlow uses similar means for pressure delivery to the cuffs as the predicate devices. Pressurized air is delivered by the pump to the cuffs using an air pump and circuit board that has up to 5 modalities. One unique modality to the PlasmaFlow is step up technology which is modality two. Modality two increases in increments of 10 and stops at 55. Then it decreases in increments of ten.

Unlike Venapro, the PlasmaFlow units visually verify the mmHg through the dual LED screen technology.

Like the *VenaPro* the PlasmaFlow cuffs are comprised of single bladder PVC chambers encased in a covering of soft, non-latex, non-woven medical fabric (a Polyester blend) or equivalent medical material for increased patient comfort and biocompatibility compliance.

As with the *Venapro* system, 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 PlasmaFlow is designed for the same intended use as the predicated device such as the *Venapro*. The comparison of the specifications demonstrates the functional equivalence of the products. ManaMed Inc. concludes that the PlasmaFlow is substantially equivalent and performs in a manner that is substantially equivalent to predicated devices.

**Non-Clinical Testing:**

Non-clinical validation, including electrical safety, EMC, Usability, Risk Analysis, mechanical integrity, environmental and life cycle testing have shown that the PlasmaFlow has performance characteristics substantially equivalent to or surpassing those of the listed predicate devices. In-house bench testing has verified equivalent pressure delivery, cuff (bladder) fill time, cycle time and overall system performance as the predicate devices listed. The results from these non-clinical tests demonstrated that the proposed PlasmaFlow meets design, safety and performance requirements; and does not raise any new concerns of safety and effectiveness.

| Testing Item | Standard and Regulations Applied | Comments |
|---|---|---|
| Biocompatibility | ISO 10993-1:2009/Cor. 1:2010(E) Biological evaluation of medical devices – Part 1: Evaluation and testing with a risk management process.<br><br>ISO 10993-5:2009 (E) Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity.<br><br>ISO 10993-10:2010(E) Biological evaluation of medical devices – Part 10: Tests for Tests for irritation and skin sensitization.<br><br>ISO 10993-12: 2012 Biological Evaluation Of Medical Devices -- Part 12: Sample Preparation And Reference Materials.<br><br>ISO/IEC 17025:2005 General Requirements for the Competence of Testing and Calibration Laboratories. | Biocompatibility tests for PlasmaFlow PF0001 were performed. PlasmaFlow passed Cytotoxicity, Sensitization, and Irritation tests. |

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| | USP 35 Biological reactivity tests, *in vitro* | |
| Electromagnetic Compatibility and Electrical Safety | IEC 60601-1: 2005-12, 3rd Edition +A1:2012 – medical electrical equipment – part 1: General Requirements for basic safety and essential performance<br><br>AAMI ES 60601-1: 2005 +A1: 2012 – Medical electrical equipment – Part 1: General Requirements for basic safety and essential performance – Deviations from IEC 60601-1: 2005<br><br>IEC 60601-1-2 Edition 3:2007-03 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility -Requirements and tests. (EN 60601-1-2)<br><br>IEC 60601-1-11: 2010 – medical electrical equipment – part 1-11: General requirements for basic safety and essential performance – collateral standard: requirements for medical electrical equipment and | EMC tests were conducted according to the same standards as the predicate. |

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| | medical electrical systems used in the home healthcare environment (EN 60601-1-11: 2010)<br><br>IEC 60601-1-6 2010 3rd edition Medical electrical equipment Part 1-6: General requirements for safety – collateral standard: Usability<br><br>IEC 62366: 2007 +A1: 2014 - Medical Devices – Application of usability engineering to medical devices (EN 62366: 2008) | |
| Software | Software verification and validation was conducted and documentation is provided. The software was considered as a "moderate" level of concern, since a failure or latent flaw in the software could directly result in serious injury to the patient or operator. | |
| Risk Management | ISO14971 Medical Devices - Application Of Risk Management To Medical Devices. (General I (QS/RM))<br>IEC 60812 Analysis Techniques for System Reliability – Procedure for Failure Mode and Effects Analysis<br>ISO 13485: 2003 – Medical Devices – Quality management systems – requirements for regulatory purposes | Manufacturing was consistent with the required mechanisms for change control, identification, and traceability. The risk management document exemplifies the process of controls in place. |
| Performance | Pressure delivery, cuff (bladder) fill time, cycle time and overall system performance as the predicate devices listed | |
| Leak, Burst, Pressure Testing | Outside testing of pressure, leak, | |

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| | and burst. Results included with full validation and similar with predicates. | |

**Clinical Testing:**

No clinical testing was performed on the PlasmaFlow to support the decision of substantial equivalence; however, test results of some predicate devices have been compared in the following published clinical studies:

*Evaluation of Intermittent Pneumatic Compression Devices* (Orthopedics 24(3):257-261, 2001);

*Venous hemodynamics after total knee arthroplasty: Evaluation of active dorsal to planar flexion and several mechanical compression devices* (Journal of Bone and Joint Surgery, November 1998)

*A Mobile Compression Device for Thrombosis Prevention in Hip and Knee Arthroplasty* (Journal of Bone and Joint Surgery, 2014)

**SUMMARY:**

The PlasmaFlow is designed for the same intended use as the predicated device such as the VENAPRO. The comparison of the specifications demonstrates the functional equivalence of the products. ManaMed Inc. concludes that the PlasmaFlow is substantially equivalent and performs in a manner that is substantially equivalent to predicated devices.