August 6, 2020

ManaMed, Inc
Bill Dai
Consultant
14271 Jeffrey Rd. #246
Irvine, California 92620

Re: K200353
Trade/Device Name: ManaFlow
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: July 3, 2020
Received: July 7, 2020

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 (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,

for Fernando Aguel
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200353

Device Name
ManaFlow

Indications for Use *(Describe)*
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

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

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: ManaFlow
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

Primary Predicate Device: ACTitouch™ Adaptive Compression Therapy system
510(k) Number: K131193
Clearance Date: June 18, 2013
Submitter: Tactile Systems Technology, Inc.

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

Predicate Device: medi pneumatic compression system (pcs) – brio (Model 651)
510(k) Number: K183631
Clearance Date: January 25, 2019
Submitter: Medi USA, LP

Predicate Device: SC-3004FC-DL Sequential Circulator
510(k) Number: K142640
Clearance Date: November 6, 2014
Submitter: Bio Compression Systems, Inc.

4. Description of Subject Device

The ManaFlow system, part numbers MFLOW51 and MFLOW52, is a portable and rechargeable prescriptive device. It is intended to be used in the home or clinical/hospital setting by or under the direction of a medical professional to apply pressure to treat lymphedema and other edematous conditions and to prevent Deep Vein Thrombosis (DVT).

The ManaFlow, supplied clean and non-sterile, utilizes the pneumatically controlled 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 attached to an inflatable cuff/sleeve. An ON/OFF button, a SET button, and a display provide for user interface. There is also a port for connecting the battery charger/AC adapter plug. The cuff component consists of multiple (four or so) air chambers/bladders encased inside a soft medical fabric or equivalent medical material for increased patient comfort and biocompatibility compliance.

In operation, the user simply turns the power on via the ON/OFF button. A cuff containing air chambers/bladders is connected to the control unit. And the control unit then inflates the cuff to the default pre-determined pressure (50 mmHg), which could be adjusted/calibrated via the SET button. The cuff pressure is monitored by an internal pressure switch and system software. Once the cuff pressure of the multiple air chambers/bladders reaches the pre-determined or adjusted level, the pump is turned OFF for a rest period, and the cuff deflates to ambient pressure through a valve inside the plastic case. After the rest period, the cycle of inflation and deflation repeats until the device is turned off.

5. Indications for Use

Prescription 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

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**	**Predicate Device**	**Predicate Device**	**Predicate Device**	**Equivalence**
510(k) Number	K200353	K131193	K160318	K183631	K142640	N/A
Submitter	ManaMed, Inc.	Tactile Systems Technology, Inc.	ManaMed, Inc.	Medi USA, LP	Bio Compression Systems, Inc.	N/A
Device Name/Model	ManaFlow	ACTitouch™ Adaptive Compression Therapy system	PlasmaFlow	medi pneumatic compression system (pcs) – brio (Model 651)	SC-3004FC-DL Sequential Circulator	N/A
Intended Use	The ManaFlow system, part	The ACTitouch™ Adaptive	The PlasmaFlow, model PF0001, is	The medi pneumatic compression system	The Bio Compression	Identical

	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 The device is intended for home, and hospital use.	Compression Therapy system provides graduated compression in both sustained and intermittent settings for use in: • Enhancing venous return • Reducing venous leg ulcer healing time • Treatment and promotion of healing of stasis dermatitis and venous stasis ulcers • Treatment of chronic venous insufficiency • Reducing edema due to venous stasis • Treatment of lymphedema	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.	(pcs)-brio is a compression device based on sequential pneumatic compression technique which is intended for the treatment of the following conditions: -Lymphedema -Venous stasis ulcers -Venous insufficiency -Peripheral edema The device is intended for home, and hospital use.	Systems' SC-3008-DL, SC-3004-DL, SC-3004FC-DL and SC-2008-DL pumps and associated garments are sequential, pneumatic compression devices intended for the primary or adjunctive treatment of primary or secondary lymphedema. These devices are also intended for the additional or alternate treatment of venous insufficiency and chronic venous stasis ulcers associated with venous insufficiency, as well as general treatment for swelling of the extremities. The devices are intended for home or hospital use.	
Prescription or OTC	Prescription	Prescription	Prescription	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	5V DC power supply (100-240 VAC input) and 3.7V rechargeable battery	115V AC, 50-60Hz	115V AC, 50-60Hz	Identical or similar
Battery Charge	Takes approximately 4 hours (from depleted state).	Takes approximately 4 hours (from depleted state).	Takes approximately 2.5 hours (from depleted state).	N/A	N/A	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: 5 Vdc @ 2 Amp)	Input: 100 - 240 Vac, 50 - 60 Hz, Output: 7.5 Vdc @ 0.9 Amp)	Input: 100 - 240 Vac, 50 - 60 Hz, Output: 5 Vdc @ 1 Amp)	115V AC, 50-60Hz	115V AC, 50-60Hz	Identical or 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	N/A	No	Identical
Compliance with Voluntary Standards?	Yes	Yes	Yes	Yes	Yes	Identical
Electrical Safety Mechanical Safety Chemical Safety Thermal Safety Radiation Safety?	Yes	Yes	Yes	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.	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.	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.	The ACTitouch System is contraindicated if the patient has: • An Ankle Brachial Pressure Index of less than 0.8; • Diagnosed or suspected acute Deep Vein Thrombosis (DVT) or pulmonary embolism; • Pulmonary edema; • Leg gangrene; • Acute thrombophlebitis; • Decompensated /Congestive Cardiac Failure; • Severe arteriosclerosis or other ischemic vascular disease; • Diabetes in association with	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.	Contraindicated for patients with acute Deep Vein Thrombosis.	Compression IS NOT recommended in the following conditions: • Infections in the limb, including cellulitis without appropriate antibiotic coverage • The presence of lymphangiosarcoma • Deep vein thrombosis (DVT) • Inflammatory phlebitis or episodes of pulmonary embolism • Congestive heart failure (CHF)	Identical or similar

	On extremities that are insensitive to pain. Where increased venous or lymphatic return is undesirable.	peripheral arterial disease; • Acute infections of the skin such as cellulitis; • Any lower limb malignancy.	On extremities that are insensitive to pain. Where increased venous or lymphatic return is undesirable.			
Target Population / Intended Users	Patients who need venous return and lymphedema treatment	Patients who need venous return and lymphedema treatment	Patients who need venous return	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	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	Non-invasive / external	Non-invasive / external	Identical
Portability	Portable, ambulant	Portable, ambulant	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 extremities	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	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	Leg	Leg	Lower limb(s) (Calf)	Leg, Arm	Leg, Arm, Vest	Identical
System management	Microprocessor	Microprocessor	Microprocessor	Microprocessor	Microprocessor	Identical
Pressure Source	Micro pump controlled by microprocessor	Micro pump controlled by microprocessor	Micro pump controlled by microprocessor	Micro pump controlled by microprocessor	Micro pump controlled by microprocessor	Identical
Operating Modes	Preset and adjustable modes	Two preset modes	Two preset modes	Adjustable modes	Preset and adjustable modes	Identical
Working Pressure	Preset at 50 mmHg and adjustable from 20 – 80 mmHg	Preset at 20 - 50 mmHg	Preset at approximately 55 mmHg	Adjustable at 20 - 80 mmHg	Preset at 60 mmHg and adjustable from 30 – 120 mmHg	Identical or similar
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 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,	When it is first switched on in the Sustained Compression Mode, the device gradually inflates, starting at the foot and working up toward the knee. Each chamber will stop inflating when the correct pressures are achieved and will hold these pressures until the device is turned off. When in Intermittent	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 seconds / leg. Each cycle consists of inflation of a bladder, followed by a rest period during which the	Stays on in a pulsing manner and then release until the user turns it off or can be set up to turn off in a range of 10 to 180 minutes	In the preset 60mmHg mode, 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 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 30 - 120 mmHg mode,	Identical or similar

	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 four chambers will then deflate to the low pressure level. This cycle of inflation and deflation will continue until the device is turn off.	Pneumatic Compression Mode, the device will perform cyclic inflation/ deflation sequences to preset gradient pressures. Once the starting pressure is reached, 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 four (4) chambers will then deflate to the low pressure level. This cycle of inflation and deflation will continue until the device is either unplugged from the Power Adapter/Charger or after two (2) hours of use.	bladder deflates and the limb relaxes without any compression.		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 four 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	Audible and visual alarms prompt recognition of system faults	Audible and visual alarms prompt recognition of system faults	Audible and/or 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	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	Clean / non-sterile	Clean / non-sterile	Identical
Leg cuff usage	Single Patient Use	Single Patient Use	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.	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 screw	Snap and screw	Snap and tube	Snap and tube	Identical or similar

Biocompatibility	Biocompatible	Biocompatible	Biocompatible	Biocompatible	Biocompatible	Identical
Software	Moderate	Moderate	Moderate	Moderate	Moderate	Identical
Dimensions	165x83x55mm	187x69x32mm	116x65x19mm	N/A	114x298x197mm	Similar
Weight Approx.	0.80kg	0.22kg	0.23kg	N/A	2.5kg	Similar
Temperature	+10 ºC (50 ºF) to +40 ºC (104 ºF)	+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)	+10 ºC (50 ºF) to +37 ºC (100 ºF)	Identical or similar
Humidity	30%-75%	0%-75%	30%-75%	15%-93%	30%-75%	Identical or similar
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.	Switch off and disconnect the Power Adapter /Charger before cleaning or disinfecting. It is recommended that the ACTitouch Undersock be replaced after a maximum of 60 washes. Machine wash hot on a gentle cycle. Air dry or tumble dry on a low-temperature setting. To clean the ACTitouch Compression Sleeve, wipe down with a soft cloth dampened with mild soap and water. Do not immerse in fluids. Air dry thoroughly. To disinfect the ACTitouch Compression Sleeve between patient use, or if there are visible biological contaminants or visible stains, the following steps are recommended: 1. Clean any visible blood or body fluids from the surface of the sleeve. 2. Thoroughly wet surface with DisCide ULTRA Disinfecting Spray. 3. Allow surfaces to remain wet for one minute and	• 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.	To clean the Control Unit: • Wipe down the system with a damp, clean cloth. • Dry thoroughly with a fresh, clean cloth. Cleaning the single person-use inflatable cuff: • Wipe down the cuff inside and out with a damp, clean cloth. Dry thoroughly with a fresh, clean cloth. • Do not machine wash or dry! • Do not dry clean!	• Clean the exterior case and tubing with a damp (not wet) cloth using mild soap and water solution once per month or as needed. • Open garment to expose all sides either by separating Velcro type hook and loop or by unzipping (depending on type of garment). • Cleaning solution should consist of 1/3 cup of laundry detergent per 1 gallon of warm tap water. Use either a large sink or plastic tub able to hold enough solution (depending on size and quantity of garments) to completely submerge the garment leaving the latch connector bars out of the water. • Garment should be soaked for 30 minutes with mild agitation every 5 to 10 minutes while keeping it below water surface. • Thoroughly rinse garment with warm tap water and allow to air dry. • Harder to remove soil on surface of garment may require additional washing by hand with a clean towel while submerged. Avoid using any abrasive materials	Identical or similar

		then allow to air dry. To clean the ACTitouch Control Unit, wipe down with a soft cloth dampened with mild soap and water. Do not immerse in fluids. Air dry thoroughly. To disinfect the ACTitouch Control Unit between patient use, or if there are visible biological contaminants or visible stains, the following steps are recommended: 1. Clean any visible blood or body fluids from the surface of the controller. 2. Thoroughly wet surface with DisCide ULTRA Disinfecting Spray. 3. Allow surfaces to remain wet for one minute and then allow to air dry.			such as scrubbing pads or chemicals that could cause damage to the exterior surface of garment. • Re-Submerge garment for 30 minutes (with exception of tubing connectors) in solution consisting of 1 cup of bleach per 1 gallon of warm tap water, again agitating garment every 5 to 10 minutes while keeping garment below water surface. Rinse garment thoroughly with warm tap water and allow to air dry. This completes the disinfecting step.	
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.	For disposal of any components of the ACTitouch System, please follow local waste regulations or consult your local institutional waste-management service or municipal waste authority.	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.	Dispose of this product in accordance with local regulations.	Medical equipment and devices should be disposed of in proper containers that meet Environmental Protection Agency standards. Check with your local, regional and national laws and regulations to see what is required.	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 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 extremities. Each cycle consists of inflation of air bladders, followed by a rest period during which the bladders deflate and relax 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. In addition, the cuff is comprised of multiple 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 skin contact components and materials of the subject device are identical to those of the legally marketed device in K160318 and K142640 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 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.