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

March 02, 2017

Recovery Force LLC
% Ms. Deborah Grayeski
Sr. Project Manager
M Squared Associates
575 8th Ave
New York, New York 10018

Re: K162481
Trade/Device Name: RF1400 Active Compression Wrap
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: January 13, 2017
Received: January 17, 2017

Dear Ms. Grayeski:

This letter corrects our substantially equivalent letter of February 16, 2017.

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 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" (21CFR 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,

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)*
K162481

Device Name
RF1400 Active Compression Wrap

Indications for Use *(Describe)*

The RF1400 Active Compression Wrap is intended to be a portable and wearable system, prescribed by healthcare professionals, to treat the following conditions by stimulating blood flow in the legs:
• Aid in the prevention of DVT (deep vein thrombosis);
• 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, chronic lymphedema, and reduction of edema in the lower limbs;
• As a prophylaxis for DVT by persons expecting to be stationary for long periods of time.
• Reduction of edema associated with soft tissue injuries, such as burns, postoperative or post-immobilization edema, or ligament sprains.
The device can be used in the home or clinical setting. The device is intended for use in an adult patient population.

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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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 5 510(k) Summary

**Submitter Information**

| | |
|---|---|
| Applicant: | Recovery Force LLC |
| | 12175 Visionary Way, Suite 117<br>Fishers, IN 46038 |
| Phone Number: | 1-866-604-6458 |
| Official Correspondent: | M Squared Associates, Inc.<br>Deborah Grayeski<br>575 8th Avenue, Suite 1212<br>New York, NY 10018<br>Phone: 703-562-9800 ext. 250<br>Fax: 703-562-9797<br>Email: dgrayeski@msquaredassociates.com |
| Date of Preparation: | February 14, 2017 |

**Device Name**

| | |
|---|---|
| Trade Name: | RF1400 Active Compression Wrap |
| Common/Usual Name: | Compressible Limb Wrap |
| Classification Name: | Compressible Limb Wrap (21 CFR 870.5800, Product code JOW) |

**Device Description**

The RF1400 Active Compression Wrap is a lightweight, portable, rechargeable battery powered, prescriptive device that helps stimulate blood flow in the lower limb through the use of intermittent sequential compression. The wrap contains nickel titanium, martensite to austenite phase change wires, using a battery-powered microprocessor to “excite” and “relax” the wires resulting in compression. The battery and microprocessor components are protectively housed in a plastic controller case that is permanently attached to the wrap. A single, touch control button interface and a RGB LED light indicator provide the user interface, and there is a port for connecting the battery charger plug. The wrap is available in a wide range of sizes XS, S, M, and L, to accommodate varying anatomy sizes.

The wrap is divided into three discrete zones which are externally applied to the limb. After one zone is fully activated for a period of time and turns off, then the next zone is activated. This cycle continues until all three zones have activated and turned off. Then the sequence is repeated after a short delay. This cycle repeats until the unit is turned off. The wrap may be used on one or both legs. When used on both legs, the wraps operate separately. The wrap is supplied with a rechargeable battery, which can be charged when not in use.

**Intended Use/Indications:**

The RF1400 Active Compression Wrap is intended to be a portable and wearable system, prescribed by healthcare professionals, to treat the following conditions by stimulating blood flow in the lower limbs:

- 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, chronic lymphedema, and reduction of edema in the lower limbs;
- As a prophylaxis for DVT by persons expecting to be stationary for long periods of time.
- Reduction of edema associated with soft tissue injuries, such as burns, postoperative or post-immobilization edema, or ligament sprains.

The device can be used in the home or clinical setting. The device is intended for use in an adult patient population.

**Contraindications:**

Do not use the RF1400 Active Compression Wrap in the following cases:

- Persons with suspected, active or untreated: deep vein thrombosis, ischemic vascular disease, blood clots, severe arteriosclerosis, pulmonary edema, severe congestive heart failure, thrombophlebitis, or an active infection
- On the legs where the cuffs (the Wrap) would interfere with the following conditions: vein ligation, gangrene, dermatitis, swollen or inflamed areas, open wounds, a recent skin graft, massive edema or extreme deformity of the leg

- Medical situations where increased venous and lymphatic return are undesirable
- On extremities that are insensitive to pain or any neuropathy
- Presence of unexplained pain.

**Predicate Devices**

The predicate devices of the RF1400 Active Compression Wrap are:

- Primary predicate: ActiveCare DVT, manufactured by Medical Compression Systems (K140755)
- Reference device: VascuTherm™, manufactured by ThermoTek, Inc. (K061866)
- Reference device: Vena Pro Vascular Therapy System, manufactured by Innovamed Health, LLC (K133274)

**Technological Characteristics Summary**

The RF1400 Active Compression Wrap is equivalent to the listed predicate devices in that all devices use a microprocessor to provide intermittent compression to simulate muscle contractions in the lower limbs aiding the return of venous flow. Like the ActiveCare and Vena Pro devices, the RF1400 Active Compression Wrap is light-weight, portable, and wraps around the lower limb. Similar to the Vena Pro device, the RF1400 Active Compression Wrap may be used on one or both legs. When used on both legs, the wraps operate separately. All devices also have similar indications for use and contraindications.

Although the subject device uses different technology to enable compression (excitation and relaxation of nickel titanium, martensite to austenite phase change wires, rather than using air delivery through tubing which is used in the predicate devices), the subject device has similar performance characteristics to the predicates in terms of cycle time and applied/on-body pressure. Both the subject device and the ActiveCare DVT device have three discrete compression zones with similar on-body pressure and cycle times (2-3 seconds of compression, with approximately 24 seconds of rest period before the cycle repeats), providing sequential compression, which cannot be changed. In all devices, compression is controlled by a microprocessor controlled system having a user interface, which in addition to controlling the system, provides battery and system information (including error notification). All compression systems are encased in soft,

non-latex fabrics for patient comfort and biocompatibility. All systems are prescription only, provided non-sterile, and are intended for single patient use.

The RF1400 Active Compression Wrap is supplied with a rechargeable battery, which can be charged when not in use, whereas the predicate devices either also use a rechargeable battery or utilize a power source that must be plugged into a wall outlet.

**Summary of Nonclinical Testing**

Nonclinical validation including electrical safety, EMC, software validation, environmental/ shipping, life cycle, and performance testing have shown that the RF1400 Active Compression Wrap has performance characteristics substantially equivalent to the listed predicate devices.

Bench testing has verified biocompatibility, surface temperature, equivalent pressure delivery, cycle time and system operation as the ActiveCare DVT listed predicate.

**Substantial Equivalence**

The RF1400 Active Compression Wrap has the same intended use and performance characteristics as the predicate devices. The results of non-clinical testing demonstrates that the device met all performance requirements and that the subject device is substantially equivalent to the predicate device.