March 21, 2021

Recovery Force, LLC
% Deborah Grayeski
Sr. Project Manager
M Squared Associates
127 West 30th Street, 9th Floor
New York, New York 10001

Re: K203052
Trade/Device Name: Movement and Compressions System (the MAC System)
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: February 16, 2021
Received: February 17, 2021

Dear Deborah Grayeski:

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)*

K203052

Device Name

Movement and Compressions System (The MAC™ System)

Indications for Use *(Describe)*

The Movement and Compressions System 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) by enhancing blood circulation; and,
- As a prophylaxis for DVT by persons expecting to be stationary for long periods of time.

During use, the system also monitors patient orientation and movement. It allows healthcare providers and users to implement individualized patient management plans for DVT prophylaxis and patient mobility protocols by utilizing data accumulated by the patient on the previous day as a benchmark. The data displayed on the device allows providers to monitor the patient's orientation and activity, which can be used to identify risk factors for hospital-acquired events linked to immobility such as: deep vein thrombosis, pressure ulcers, pneumonia, atrophic muscles, and delirium.

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.

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510(K) SUMMARY

SUBMITTER: Recovery Force LLC
10022 Lantern Rd., Suite 100
Fishers, IN 46037

CONTACT: Deborah Lavoie Grayeski
M Squared Associates, Inc.
127 West 30th Street, 9th Floor
New York NY 10001
Ph. 347-307-6951/202-550-7395
Fax. 703-562-9797
Email. dgrayeski@msquaredassociates.com

DATE PREPARED: **March 17, 2021**

DEVICE:

Proprietary Name:	Movement and Compressions System (The MAC™ System)
Common Name:	Compressible Limb Sleeve
Classification Name:	Compressible Limb Sleeve, 21 CFR 870.5800
Regulatory Class:	Class II
Product Code:	JOW

PREDICATE AND REFERENCE DEVICE:

Primary Predicate: Medical Compression Systems (DBN) Ltd's ActiveCare DVT System, K140755

Reference Devices: Recovery Force RF1400 Active Compression Wrap, K162481
Centauri Medical, Inc., DynaSense System, K130752

Neither the predicate nor reference devices has been subject to a recall.

DEVICE DESCRIPTION:

The Movement and Compressions System (The MAC™ System) is a prescriptive, portable, rechargeable-battery powered, intermittent compression device designed to stimulate blood flow in the lower limb. The MAC System consists of the MAC Strap, MAC Charging Hub, and MAC Controller. The MAC Strap is a disposable single-

patient use strap that is wrapped around the patient's calf muscle. The MAC Controller houses a rechargeable battery, DC motor, gyroscope sensor, and microprocessor that is attached to the strap during use. The battery is removed from the controller for charging in the supplied MAC Charging Hub when not in use.

Compression is applied to the calf, immediately below the knee, by intermittent application of mechanical force by the device strap. When the strap is contracted, compression is applied to the patient's calf muscle. When the strap is retracted, compression force is released from the patient's calf muscle. Since mechanical force is used to provide intermittent compression, the system does not require a powered air supply, so the risk of aerosolization of potential contaminants or germs is mitigated as there is no blowing air. There are no air connections or pneumatic pumps to clean between patients.

The MAC system also monitors and displays patient orientation and movement information. This data is stored in a RFID tag in the MAC Strap. When the MAC Controller is connected to the MAC Strap, and functioning, all DVT prophylaxis compliance data, orientation and movement data is synced between the controller and the strap using Radio Frequency Identification (RFID) communication and stored between them.

INDICATIONS FOR USE:
The Movement and Compressions System 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) by enhancing blood circulation; and,
- As a prophylaxis for DVT by persons expecting to be stationary for long periods of time.

During use, the system also monitors patient orientation and movement. It allows healthcare providers and users to implement individualized patient management plans for DVT prophylaxis and patient mobility protocols by utilizing data accumulated by the patient on the previous day as a benchmark. The data displayed on the device allows providers to monitor the patient's orientation and activity, which can be used to identify risk factors for hospital-acquired events linked to immobility such as: deep vein thrombosis, pressure ulcers, pneumonia, atrophic muscles, and delirium.

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

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

A comparison of the technological characteristics between The MAC System to the predicate and reference devices is presented in Table 1.

Table 1. Comparison of the technological characteristics between The MAC System to the predicate and reference devices.				
Company	**Recovery Force**	**Medical Compression Systems**	**Recovery Force**	**Centauri Medical, Inc.**
Device	The MAC System (Subject Device)	ActiveCare DVT System (Primary Predicate)	Recovery Force RF1400 Active Compression Wrap (Reference Device)	DynaSense System (Reference Device)
510(k) Number	TBD	K140755	K162481	K130752
Classification Regulation	Class II, (21 CFR 870.5800) Compressible Limb Sleeve	Class II, (21 CFR 870.5800) Compressible Limb Sleeve	Class II, (21 CFR 870.5800) Compressible Limb Sleeve	Class I, (21 CFR 880.2400) Bed-patient monitor
Product Code	JOW Subsequent code: KMI	JOW	JOW	KMI
Device Description	The Movement and Compressions System (The MAC™ System) is a prescriptive, portable, rechargeable-battery powered, intermittent compression device designed to stimulate blood flow in the lower limb. The MAC System consists of the MAC Strap, MAC Charging Hub, and MAC Controller. The MAC Strap is a disposable single-patient use strap that is wrapped around the patient's calf muscle. The MAC Controller houses a rechargeable battery, a small DC motor, a 6-axis gyroscope sensor, and microprocessor that is attached to the strap during use. The battery is removed from the controller for charging in the supplied MAC Charging Hub when not in use. Compression is applied to the calf, immediately below the knee, by intermittent application of mechanical force by the device strap. When the strap is contracted, compression is applied to the	The ActiveCare+DTx, ActiveCare+SFT and ActiveCare DVT Systems are prescriptive, pneumatic compression Systems designed to apply sequential compression to the lower limb. The control units of the Systems provide the user with several treatment options: compression of the foot - single or double, compression of the calf - single or double, compression of the thigh - single or double, and combined compression of any combination of two sleeves. The foot compression program is an intermittent pressure pulse application to a single celled foot sleeve. The calf and thigh compression program is a sequential intermittent application of a pressure to a three-celled cuff sleeve.	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	DynaSense is a patient monitoring system that has been designed for use in hospitals, nursing homes, or other patient care facilities to aid standard care procedures for patients who are susceptible to pressure ulcers. The system monitors and reports patient activity and orientation as well as alerts the user (i.e., healthcare provider) when activity levels deviate from parameters set by healthcare providers. DynaSense is comprised of Patient Sensors, Relay Antennas, a USB RE Transceiver, Mesh Network Server Software, and User Interface software. Each Patient Sensor is associated with a single patient, such that the patient's orientation and activity can be monitored. Data collected by the Patient Sensor is automatically communicated wirelessly to a nearby Relay Antenna, which subsequently relays these data to be displayed on the User Interface and maintained in a database. The

	patient's calf muscle. When the strap is retracted, compression force is released from the patient's calf muscle. Since mechanical force is used to provide intermittent compression, the system does not require a powered air supply, so the risk of aerosolization of potential contaminants or germs is mitigated as there is no blowing air. There are no air connections or pneumatic pumps to clean between patients. The strap is available in two sizes: Standard and XL. The system may be used on one or both legs. When used on both legs, the wraps operate separately. The MAC System also monitors and displays patient orientation and movement information (see DynaSense reference device, K130752). This data is stored in a RFID tag in the MAC Strap. When the MAC Controller is connected to the MAC Strap, and functioning, all DVT prophylaxis compliance data, orientation and movement data is synced between the strap and controller using Radio Frequency Identification (RFID) communication and stored between them.		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.	system's Relay Antennas that are plugged into electrical outlets on the walls of the facility and the USB RIF Transceiver that is plugged into the computer, on which the Mesh Network Server Software is installed or accessed, form a wireless network that allows data to be transmitted for display. The Mesh Network Server Software manages this network of Relay Antennas and USB REF Transceiver and collects the data from the Patient Sensors to allow monitoring of multiple patients on a single screen within the User Interface.

Intended Use	Lower limb compression	Lower limb compression	Lower limb compression	Monitor orientation and activity.
Indications for Use	The Movement and Compressions System 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) by enhancing blood circulation; and, • As a prophylaxis for DVT by persons expecting to be stationary for long periods of time. During use, the system also monitors patient orientation and movement. It allows healthcare providers and users to implement individualized patient management plans for DVT prophylaxis and patient mobility protocols by utilizing data accumulated by the patient on the previous day as a benchmark. The data displayed on the device allows providers to monitor the patient's orientation and activity, which can be used to identify risk factors for hospital-acquired events linked to immobility such as: deep vein thrombosis, pressure ulcers, pneumonia, atrophic muscles, and delirium.	The ActiveCare DVT, ActiveCare+SFT and ActiveCare+DTx Systems are prescriptive devices that induce Continuous Enhanced Circulation Therapy of the lower limbs. The Systems are intended for use in: • Preventing Deep Vein Thrombosis (DVT). • Enhancing blood circulation. • Diminishing post-operative pain and swelling. • Reducing wound-healing time. • Treatment and assistance in healing: stasis dermatitis; venous stasis ulcers; arterial and diabetic leg ulcers. • Treatment of chronic venous insufficiency. • Reducing edema.	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.	DynaSense monitors orientation and activity of patients susceptible to pressure ulcers. It allows healthcare providers to implement individualized turn management plans and continuously monitor each patient. DynaSense provides alerts when patient orientation or activity deviates from parameters set by healthcare providers. The device is intended for use in medical, nursing and long-term care facilities including independent living, assisted living and rehabilitation facilities.

	The device can be used in the home or clinical setting. The device is intended for use in an adult patient population.			
Target Population/ Where used	Home or clinical setting.	Home or clinical setting.	Home or clinical setting.	Medical, nursing and long-term care facilities including independent living, assisted living and rehabilitation facilities.
Anatomical Site	Lower leg	Lower leg	Lower leg	Sensor attaches to patient's sternum.
Principle of Operation	Intermittent compression via DC motor strap tightening. Patient orientation and movement monitored using a 6-axis gyroscope sensor/step counter.	Sequential, intermittent, pneumatic compression	Nickel titanium, martensite to austenite phase change wires, resulting in compression.	Patient orientation and activity monitored using a patient sensor.
Weight	11 oz	1.65 lb	1.00 lb	Unknown
Dimension	6 H (at largest part) x 22.25 L (Standard size), 0.3 thick (Excluding Controller) inches.	5.3 x 5.3 x 2.4 inches	9 H x 20 L (Small size), 0.3 thick (excluding controller) inches	Sensor 1.8" x 2.0"
Cycle Time	60 seconds consisting of the following sequence: • Compression for ≤1 second • Hold for 1 second • Compression release for ≤ 2 seconds • No compressions for ~ 56 seconds	30 seconds consisting of the following sequence: • Bottom Zone inflation for 2-3 seconds • Middle Zone inflation for 2-3 seconds • Top Zone inflation for 2-3 seconds Cuff deflates to a total cycle time of 30 seconds, then cycle restarts.	30 seconds consisting of the following sequence: • Bottom Zone compression for 2 seconds • Middle Zone compression for 2 seconds • Top Zone compression for 2 seconds • No compressions for 24 seconds	N/A, this device is solely referenced for its use in monitoring patient orientation and activity.
Biocompatibility	Biocompatible	Biocompatible	Biocompatible	Biocompatible
Bilateral treatment option	Yes	Yes	Yes	N/A, this device is solely referenced for its use in monitoring patient orientation and activity.

Single Patient Use	Yes (Controller and Charging Hub that only have transient contact with the patient are reusable)	Yes	Yes	Yes (sensor that adheres to the patient is single use, while other components for transmitting and displaying the information are reusable)
Sterility	Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile
Power Requirements (Battery Spec's)	3.6V; 2.9Ah; 10.44Wh Li-Ion 18650 single cell rechargeable battery pack	7.2 V; 1.8Ah; 12.96Wh Ni-MH battery 6 cell rechargeable battery pack	14.4V; 2.0Ah; 28.8Wh Li-Ion 18650 four-cell rechargeable battery pack	Unknown

The differences between the MAC System and the predicate device does not affect the intended use and does not raise new questions of safety and effectiveness. The MAC System is equivalent to the listed predicate device in that they both use a microprocessor to provide intermittent compression to simulate muscle contractions in the lower limbs aiding the return of venous flow. Intermittent compression is the technological principle for both the subject and predicate/reference devices. Both devices have 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 and provided non-sterile. The MAC System is supplied with a rechargeable battery, which can be charged when not in use, whereas the predicate devices use a rechargeable battery or utilize a power source that must be plugged into a wall outlet. Both devices are light-weight, portable and wrap around the lower limb. Like the reference device, the MAC System can be used on one or both legs. When used on both legs, the wraps operate separately.

In addition to compression, the MAC System also monitors and reports patient orientation and movement. While the primary predicate does not provide this functionality, there are other devices that include similar functionality. Table 2 provides a comparison of the characteristics between the MAC System and the DynaSense System.

Table 2. Technological comparison to bed-patient monitor reference device.

	Recovery Force The MAC System	**Centauri Medical, Inc.** DynaSense System (Reference Device) K130752, Class I device	**Remarks**
Clinical Application	Sensor is located in the MAC Controller that is attached to the disposable MAC Strap which is wrapped around the patient's lower leg.	Non-invasive adherence to patient's skin	Similar to Reference Device: both sensors are placed non-invasively, near the surface of the patient's skin.
Principle of Operation	A gyroscope monitors patient orientation (horizontal versus vertical) and movement (steps).	Patient sensor that monitors patient orientation and movements (based upon publicly available information).	Similar to Reference Device: both devices monitor patient orientation and movement.
Device Output	Monitors and reports body orientation and movement. This information is displayed on a User Interface.	Monitors and reports body orientation and movement. This information is communicated wirelessly through an antenna, saved on a server and displayed on a User Interface.	Similar to reference device: both devices display the information on a user interface.

PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the MAC Strap was conducted in accordance with ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process". The battery of testing included the following tests:

- Cytotoxicity testing
- Closed Patch Sensitization testing
- Primary Skin Irritation testing

Based upon this testing, The MAC Strap is considered non-cytotoxic, a non-sensitizer, and produces no dermal irritation.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the MAC System and Charging Hub. Testing was successfully performed according to all applicable portions of:

- IEC 60601-1-2:2014/Edition 4.0 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral

Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1:2005 (3rd Edition), Corr. 1:2006, Corr. 2:2007, A1:2012 (IEC 60601-1: 2012 reprint) - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11 Medical electrical equipment - Part 1-11, Edition 2.0 2015-01: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 60601-1-6 Medical electrical equipment - Part 1-6, Edition 3.1 2013-10: General requirements for basic safety and essential performance - Collateral standard: Usability

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "minor" level of concern since failures, malfunction or latent design flaws are unlikely to cause any injury to the patient or operator.

Performance Testing

Nonclinical verification and validation of performance was also performed to establish substantial equivalence to the listed predicate device. Testing was successfully performed as follows:

- Verification of strap elasticity and shear strength
- MAC Controller and Charging Hub electrical verification
- Verification of battery pack safety and performance according to applicable standards
- Compliance with established requirements applicable to radiofrequency and radiated emissions testing
- Functionality and reliability testing
- Performance testing of the subject device and predicate device to evaluate blood flow increase over baseline. Performance testing also evaluated accuracy of mobility data and strap slippage.
- Usability testing

CONCLUSION

The MAC System has the same intended use and similar performance characteristics as the predicate devices. The results of non-clinical and usability testing demonstrates that

the device met all performance requirements and that the subject device is substantially equivalent to the predicate device.