January 25, 2019

Medi USA, LP
% Mark Job
Regulatory Technology Services, LLC
1394 25th Street, Nw
Buffalo, Minnesota 55313

Re: K183631
Trade/Device Name: medi pneumatic compression system (pcs) – brio (Model 651)
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible limb sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: December 19, 2018
Received: December 26, 2018

Dear Mark Job:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183631

Device Name
medi pneumatic compression system (pcs) – brio (Model 651)

Indications for Use *(Describe)*
The medi pneumatic compression system (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

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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510k SUMMARY

This 510(k) summary is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

I. SUBMITTER

MEDI USA, LP
6481 Franz Warner Pkwy.
Whitsett, NC 27377

Phone: (336) 449 4440

Contact Person: Glenn Anderson
Date Prepared: December 5, 2018

II. DEVICE

Name of Device: medi pneumatic compression system (pcs) – brio (Model 651)

Common or Usual Name: Sleeve, Limb, Compressible

Classification Name: Compressible Limb Sleeve (21 CFR 870.5800)
Regulatory Class: II,
Product Code: JOW

III. PREDICATE DEVICES

Primary- CircuFlow 5200 Series Sequential Compression Device (K101523)

The predicate device has not been subject to a design-related recall

IV. DEVICE DESCRIPTION

The medi pneumatic compression system (pcs) – brio (Model 651) system consists of a medi pcs pump device a medi pcs air inflatable sleeve with air hose and connectors. The pump device, air hose, and sleeves are all non-sterile and single patient use.

The medi pcs brio (Model 651) device is an intermittent mechanical gradient compression pump that includes a pressure control unit (PCU) with two connection points for air inflatable sleeves with air hose and connectors, a power switch and a wall power connection for standard 125v AC Power. The PCU provides compression with short cycles of pneumatic pressure applied in short, steady cycles. The air compressor distributes calibrated gradient pressure through a series of regulators to original compression sleeves containing either 6 or 8 inflatable chambers to be externally applied over the affected extremity of the patient. The medi pcs brio (Model 651) is a basic model and is adjustable and limits the different treatment pressures and treatment

times according to physician prescription.

The medi pcs brio (Model 651), air hose and sleeves together may only be distributed, sold and operated as a prescribed device. The device must be operated only with a new, original manufacturer limb sleeves, and all pads that are non-sterile, single patient use.

The medi pcs brio (Model 651) is used exclusively with air hose and medi pcs compression sleeves to fit both the upper and lower extremities. The medi pcs brio (Model 651)) device, air hoses and air inflatable sleeves together may only be distributed, sold and operated as a prescribed device.

V. INDICATIONS FOR USE

The medi pneumatic compression system (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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Description	**Subject Device-medi pcs brio (Model 651)**	**Predicate- CircuFlow 5200**
510(k)	TBD (assigned by FDA)	K101523
Medical Device Classification	Same	Class II
Product Code	Same	JOW
Regulation Classification	Same	870.5800
Review Panel	Same	Cardiovascular
Intended Use	Same	Intermittent Sequential Pneumatic Compression
Indications for Use	The medi 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	The CircuFlow 5200 Series Sequential Compression Pump is a compression device based on sequential pneumatic compression technique which is intended for the treatment of the following conditions: -Lymphedema

	-Peripheral edema The device is intended for home, and hospital use	-Venous stasis ulcers -Venous insufficiency -Peripheral edema The device is intended for home, and hospital use
Prescription Use Only	Same	Yes
Compression Type	Same	Adjustable Distal Pressure, Gradient, Sequential
Regulation Description	Same	Compressible Limb Sleeve
Mode	Same	Continuous
# of Inflatable Sleeve Chambers	6 or 8 per sleeve	4 or 8 per sleeve
Pump Distal Sleeve Chamber Pressure Range	20 – 80 mm Hg	25 – 120 mm Hg
Default Distal Sleeve Chamber Pressure	50 mmHg Distal	45 mmHg Distal
Inflation time	3-5 seconds per chamber, dependent on pressure setting & sleeve size	Adjustable 5 – 20 seconds per chamber
Deflation time	10 seconds	12 seconds
Cycle Time	28-46 seconds, dependent on pressure settings and sleeve model.	Adjustable 32 – 92 seconds
Therapy Time	Adjustable, 10 – 180 minutes	Adjustable 15 – 180 minutes
UL Mark	Applied Part Type BF Protection against Electrical Shock: Class II	Applied Part Type B Protection against Electrical Shock: Class I
Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-11 ISO 10993 ISO 14971 IEC 62304 ISO 13485	IEC 60601-1-1 IEC 60601-1-2 UL 60601-1 ISO 10993 ISO 14971
Single Patient Use	Same	Yes

Adjustable Distal Pressure, Gradient, Sequential compression is the technological principle for both the subject and predicate device. Both compression systems are used to prevent pooling of blood in a limb by inflating periodically a sleeve around the limb. Both compression systems are adjustable distal pressure, gradient, sequential type and enables different treatment pressures and treatment times according to physician prescription.

At a high level, the subject and predicate device are based on the following same technological features and operational elements:

- Similar pump with similar principals of operation
- Similar sleeve design and materials

All devices consist of electrically generated sources of compressed air, tubing to convey the pressurized air to the sleeve and pressure is applied cyclically for a specified period of time.

VII. PERFORMANCE DATA

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

Biocompatibility testing

Biocompatibility tests were selected based on the 510(k) Memorandum - #G95-1 "Use of International
Standard ISO-10993", Table 1 Initial Evaluation Tests for Consideration. The test article of Nylon 210D (ID 07082016) is used for manufacturing all sleeves. Based on intended use and contact, this nylon 210D material is considered a "Surface Device" for "Skin" and has a prolonged contact duration of 24h to 30 days.

Based on the ISO 10993-1 testing matrix, Cytotoxicity, Sensitization, and Irritation studies were required according to the following ISO standards and Good Laboratory Practices (GLP), (21 CFR Part 58).

- AAMI / ANSI / ISO 10993-1: Biological evaluation of medical devices -- Part 1: Evaluation and testing
- AAMI / ANSI / ISO 10993-5: Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity
- AAMI / ANSI / ISO 10993-10: Biological evaluation of medical devices -- Part 10: Tests for irritation and sensitization

Electrical safety and electromagnetic compatibility (EMC)

The medi pcs brio (Model 651) conforms to the following standards

- Electrical Safety General Requirements for basic safety and essential performance per ANSI/AAMI 60601-1
- Electrical Safety Collateral Standard per ANSI/AAMI 60601-1-11
- EMC requirements and tests per IEC 60601-1-2

Software Verification and Validation
The medi pcs brio (Model 651) conforms to the following standard, based on its identified level of moderate concern

- IEC 62304:2006 Medical Device Software

Bench Performance

Bench and laboratory testing was performed and assures that the product meets its specifications. The manufacturer believes that the technological characteristics of the medi pcs brio (Model 651) are substantially similar to those of the predicate device. The performance tests performed include assessment of:

- Inflation and Deflation Time Performance
- Treatment time Performance
- Pressure Performance
- Burst Pressure Performance
- Pressure Gradient Performance
- Software Integration - Graphical User Interface Navigation Performance
- Software Integration – Pressure Calibration Performance
- Safety – Errors & Alarm Performance

VIII. CONCLUSION

Based on their same intended use, safety and performance testing results and the compliance with the acceptable voluntary standards and comparison to the predicate in terms of features and characteristics; we conclude that the proposed subject device, the medi pcs brio (Model 651) is substantially equivalent to the identified predicate, since the subject device has the same technical and performance characteristics as the predicate device. Performance testing results for the proposed devices do not raise any new safety and/or effectiveness issues.