



July 7, 2022

medi USA, L.P.  
% Prithul Bom  
Most Responsible Person  
Regulatory Technology Services, LLC  
1000 Westgate Drive, Suite 510k  
Saint Paul, Minnesota 55114

Re: K221654

Trade/Device Name: medi pneumatic compression system (pcs)-genius (Model 652)  
Regulation Number: 21 CFR 870.5800  
Regulation Name: Compressible limb sleeve  
Regulatory Class: Class II  
Product Code: JOW  
Dated: June 6, 2022  
Received: June 7, 2022

Dear Prithul Bom:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Nicole Gillette  
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

Form Approved: OMB No. 0910-0120  
Expiration Date: 06/30/2023  
See PRA Statement below.

## Indications for Use

510(k) Number (*if known*)

K221654

Device Name

medi pneumatic compression system (pcs) – genius (Model 652)

Indications for Use (*Describe*)

The medi pneumatic compression system (pcs) genius 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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Section 5

**510k SUMMARY**

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

**I. SUBMITTER**

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Contact: Moses Lipshaw  
Date Prepared: April 6, 2022

**II. DEVICE**

Name of Device: medi pneumatic compression system (pcs) genius (Model 652)

Common or Usual Name: Compressible Limb Sleeve

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

**III. PREDICATE DEVICE**

Name of Device: medi pneumatic compression system (pcs) – brio (Model 651) (K183631)

Common or Usual Name: Compressible Limb Sleeve

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

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

**IV. DEVICE DESCRIPTION**

The medi pneumatic compression system (pcs) genius (Model 652) 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 genius (Model 652) 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 in 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, 8, or 10 inflatable chambers to be externally applied over the affected extremity of the patient. The medi pcs genius (Model 652) is adjustable and limits the different treatment pressures and treatment times according to clinician prescription.

The medi pcs genius (Model 652) is used exclusively with air hose and medi pcs compression sleeves to fit both the upper and lower extremities. The medi pcs genius (Model 652) device, air hoses and air inflatable 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 sleeve(s) that are non-sterile and single patient use.

## V. INDICATIONS FOR USE

The medi pneumatic compression system (pcs) genius 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 genius (Model 652)	Predicate: medi pcs brio (Model 651)
510(k)	TBD (assigned by FDA)	K183631
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	Same	The medi pneumatic compression system (pcs) 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
Prescription Use Only	Same	Yes
Compression Type	Adjustable Distal Pressure & Gradient Sequential or Peristaltic Adjustable pressure by chamber	Adjustable Distal Pressure & Gradient Sequential
Regulation Description	Same	Compressible Limb Sleeve
Mode	Same	Continuous
# of Inflatable Sleeve Chambers	6, 8, or 10 per sleeve	6 or 8 per sleeve
Pump Distal Sleeve Chamber Pressure Range	20 – 100 mmHg	20 – 80 mmHg
Default Distal Sleeve Chamber Pressure	Same	50 mmHg Distal
Inflation time	1-5 seconds per chamber, dependent on pressure setting & sleeve size	3-5 seconds per chamber, dependent on pressure setting & sleeve size
Deflation time	Pressure based, deflates to 10mmHg or lower.	Time based, 10 seconds
Cycle Time	Sequential: 15-38 seconds, Peristaltic: 50-170 seconds, dependent on pressure settings and sleeve model(s).	Sequential: 28-46 seconds, dependent on pressure settings and sleeve model(s).
Therapy Time	Same	Adjustable, 10 – 180 minutes
UL Mark	Same	Applied Part Type BF Protection against Electrical Shock: Class II
Standards	Same	IEC 60601-1, IEC 60601-1-2, IEC 60601-11, ISO 10993, ISO 14971, IEC 62304, ISO 13485
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. Each compression systems are adjustable distal pressure, gradient, sequential type and enables different treatment pressures and treatment times according to clinician 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 time period.

## **VII. NON-CLINICAL TESTING**

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

### **Sterilization**

The medi pcs genius (Model 652) is provided non-sterile.

### **Shelf-Life**

Accelerated aging studies were conducted on the pressure control unit (PCU), sleeves and connectors and demonstrated all remain functional for a minimum of 5 years supporting the medi pcs genius (model 652) shelf-life stability.

### **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. Based on intended use and contact, the exterior sleeve material is considered a "Surface Device" for "Skin" and has a permanent cumulative contact duration of greater than 30 days when used for one hour daily over the course of a 3 year sleeve lifespan.

Based on the ISO 10993-1 testing matrix, Cytotoxicity, Sensitization, and Irritation studies were required and conducted on the exterior sleeve material 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

Results demonstrated conformance to all standards.

### **Electrical safety and electromagnetic compatibility (EMC)**

The medi pcs genius (Model 652) was tested and 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 genius (Model 652) conforms to the following standard, based on its identified moderate level of concern:

- IEC 62304:2006 Medical Device Software

## **Bench Performance**

Bench and laboratory testing was performed and assures that the product meets its specifications. The sponsor believes that the technological characteristics of the medi pcs genius (Model 652) 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
- Packaging Test Performance
- Use Life Test Performance

## **Summative Usability**

Usability testing and evaluation of end-users confirmed the medi pcs genius (Model 652) Operators Manual is appropriate and suitable for both professional users and non-medical operators for performing compression therapy based on sequential pneumatic compression technique.

## **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 medi pcs genius (Model 652) 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 device do not raise any new safety and/or effectiveness issues.