July 10, 2020

B & J Manufacturing Ltd
℅ Fu Ailing
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
Room 1713A, 17F, Black A, Time Square, Xili Town
Shenzhen, Guangdong 518055
China

Re: K200568
Trade/Device Name: B&J MHP800 Deep Vein Thrombosis Prevention System
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: May 5, 2020
Received: June 8, 2020

Dear Fu Ailing:

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)*
K200568

Device Name

B&J MHP800 Deep Vein Thrombosis Prevention System

Indications for Use *(Describe)*

The B&J MHP800 deep vein thrombosis prevention system is intended to be an easy to use portable system, prescribed by a physician, to help prevent the onset of DVT in patients by stimulating blood flow in the extremities (simulating muscle contractions).

The device can be used in the home or clinical settings to:
- Aid in the prevention of DVT;
- Enhance blood circulation;
- Diminish post-operative pain and swelling;
- Reduce wound healing time;
- Aid in the treatment of: stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency and reduction of edema in the lower limbs;
- As a prophylaxis for DVT by persons expecting to be stationary for long periods of time

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

[As required by 21 CFR 807.92]

1. Date Prepared [21 CFR807.92 (a) (1)]

February 10, 2020

2. Submitter's Information [21 CFR807.92 (a) (1)]

Name of Sponsor: B&J Manufacturing Ltd.

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3. Trade Name, Common Name, Classification [21 CFR807.92 (a) (2)]

Trade Name/Model: B&J MHP800 Deep Vein Thrombosis Prevention System

Common Name: MHP800 DVT Compression Device

Classification Name: Sleeve, Limb, Compressible

Regulation Number: 21 CFR 870.5800

Product code: JOW

Classification Panel: Cardiovascular

Device Class: II

4. Identification of Predicate and Reference Devices [21 CFR 807.92(a) (3)]

The identified predicate within this submission is as follows:

Devon Medical Products, Cirona 6300 Disposable Deep Vein Thrombosis (DVT)

Prevention System has been cleared by FDA through 510(k) No. K151189 (Decision Date - September 18, 2015).

The identified reference devices within this submission are as follows:
Eezcare Medical Corp, Ezvena IPC, Ezvena SQS has been cleared by FDA through 510(k) No. K191937 (Decision Date - January 29, 2020).
Devon Medical Inc., Cirona 6200 Deep Vein Thrombosis Prevention System has been cleared by FDA through 510(k) No. K141578 (Decision Date - June 27, 2014).

5. Description of the Device [21 CFR 807.92(a) (4)]

The B&J MHP800 Deep Vein Thrombosis Prevention System is an intermittent pneumatic compression system that aids in the prevention of deep vein thrombosis a potentially life-threatening condition which can lead to pulmonary embolism. The DVT compression device is a non-invasive mechanical prophylactic system that helps decrease the incidence of deep vein thrombosis. The system consists of a pair of pump and sleeve assemblies.

The DVT pump will inflate each leg cuff to a preset pressure of 45mmhg for 12 seconds, and followed by 48 seconds of deflation period once the pressure is reached. This happens once every minute. The cycles are repeated on each unit until the power is turned off.

Internal rechargeable batteries allow the MHP800 to be completely portable to prevent interruptions in treatment.

6. Intended Use [21 CFR 807.92(a)(5)]

The B&J MHP800 deep vein thrombosis prevention system is intended to be an easy to use portable system, prescribed by a physician, to help prevent the onset of DVT in patients by stimulating blood flow in the extremities (simulating muscle contractions).

The device can be used in the home or clinical settings to:
- Aid in the prevention of DVT;
- Enhance blood circulation;
- Diminish post-operative pain and swelling;
- Reduce wound healing time;
- Aid in the treatment of: stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency and reduction of edema in the lower limbs;

- As a prophylaxis for DVT by persons expecting to be stationary for long periods of time

7. Technological Characteristics [21 CFR 807.92(a)(6)]

MHP800 DVT Pump

General Specification:			
Model No.	MHP800		
Size	145mm (L)*61mm(W)*36mm(H)		
Weight	0.2 kg		
AC/DC Adapter	AC Input: 100V-240V 50/60Hz; DC Output: 5V, 2A (2 plugs)		
Mode of Operation/ Operating Time	Continuous / 8 hours		
Battery Type	Lithium Battery 7.4V 650mAh (rechargeable)		
Charging Time	2.5 Hours		
Pressure Range	45 ±10% mmHg (default)		
Reset Time	60s		
Humidity	Operation: 15% to 93 % (without condensation)		
	Storage & Transportation: 10% to 95% (without condensation)		
Air pressure	Operation: 525mmHg to 795mmHg		
	Storage & Transportation: 165mmHg-805mmHg		
Temperature	Operation: +5° C (41° F) to +40° C(104° F)		
	Storage & Transportation: -20° C (-4° F) to +55° C (131° F)		
Sleeve component:			
Model Name	Description		Circumference
MHP801M	Medium	Latex Free Calf Garment (Pair)	Up to 18''

8. Substantial Equivalence [21 CFR 807.92(b) (1) and 807.92]

8.1 Intended use:

Table 1 Intended Use Comparison

ID	Comparison Item	Proposed Device B&J DVT Prevention System (MHP800)	Predicate Device Devon DVT Prevention System (Cirona 6300)
1	**510(K) No.**	To be assigned	K151189
2	**Intended Use**	The B&J MHP800 deep vein thrombosis prevention system is intended to be an easy to use portable system, prescribed by a physician, to help prevent the onset of DVT in patients by stimulating blood flow in the extremities (simulating muscle contractions). The device can be used in the home or clinical settings to: - Aid in the prevention of DVT; Enhance blood circulation; - Diminish post-operative pain and swelling; - Reduce wound healing time; - Aid in the treatment of: stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency and reduction of edema in the lower limbs; - As a prophylaxis for DVT by persons expecting to be stationary for long periods of time	The Cirona 6300 disposable deep vein thrombosis prevention system is intended to be an easy to use portable system, prescribed by a physician, to help prevent the onset of DVT in patients by stimulating blood flow in the extremities (simulating muscle contractions). The device can be used in the home or clinical settings to: · Aid in the prevention of DVT; Enhance blood circulation; · Diminish post-operative pain and swelling; · Reduce wound healing time; · Aid in the treatment of: stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency and reduction of edema in the lower limbs; · As a prophylaxis for DVT by persons expecting to be stationary for long periods of time
3	**Type of use**	Prescription Use	Prescription Use

8.2 Comparison table

Table 2 General Comparison between MHP800 and Cirona 6300

ID	Comparison Item	Proposed Device B&J DVT Prevention System (MHP800)	Predicate Device Devon DVT Prevention System (Cirona 6300)	Explanation of Difference
4	**General Specification**			
4.1	Size	145 *61*36(mm)	65 *130*30(mm)	Different but does not raise any new issue of substantial equivalence
4.2	Weight	0.2 kg	0.3 kg	Different but does not raise any new issue of substantial equivalence
4.3	AC/DC Adapter	AC Input: 100V-240V 50/60Hz; DC Output: 5V, 2A (2 plugs)	AC Input: 100V-240V 50/60Hz; DC Output: 5V, 2A (2 plugs)	-
4.4	Mode of Operation/ Operating Time	Continuous / 8 hours	Continuous / 8 hours	-
4.5	Battery Type	Lithium Battery 7.4V 650mAh (rechargeable)	Lithium Battery 3.7V 1350mAh (rechargeable)	Different but does not raise any new issue of substantial equivalence; Refer to K151189 and K170814.
4.6	Charging Time	2.5 Hours	3 Hours	Different but does not raise any new issue of substantial equivalence; Refer to K151189 and K170814.

4.7	Pressure Range	45±10% mmHg (default)	50±5 mmHg (default)	Different but does not raise any new issue of substantial equivalence; Refer to K191937.
4.8	Reset Time	60s	50s	Different but does not raise any new issue of substantial equivalence; Refer to K141578.
4.9	Applied Mode of Pressure	Intermittent	Intermittent	-

It is clear that MHP800 is as safe and effective as the predicate by comparing above technological characteristics.

8.3 Non-clinical Testing

The following safety and performance tests were conducted to assess MHP800 DVT compression device.

- Biocompatibility
- Software validation
- Electromagnetic compatibility and electrical safety
- Reliability
- Performance
  - System level software
  - Pressure accuracy
  - Cycle time
  - Bladder burst
  - Leak

All the test results demonstrate MHP800 DVD compression device meet the requirements of its predefined acceptance criteria and intended use.

9. Conclusion [21 CFR 807.92(b) (3)]

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, B&J Manufacturing Ltd. concludes that:

- The intended use of MHP800 is totally same as that of the predicate device.
- The technological characteristics differences between MHP800 and Cirona 6300 do not affect the safety and effectiveness, no new risk is raised.
- Demonstrated by the safety and performance tests, the characteristics of MHP800 is equivalent to those of the predicate device.