July 8, 2020

B & J Manufacturing Ltd.
% Fu Ailing
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
Room 1713A, 17F, Block A, Time Square, Xili Town
Shenzhen, 518055 Cn

Re: K200154
Trade/Device Name: B&J DVT Compression Devices MHH800/MHH800SQ
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: December 28, 2019
Received: January 22, 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)*

K200154

Device Name
B&J DVT Compression Devices MHH800/MHH800SQ

Indications for Use *(Describe)*
The B&J Manufacturing Ltd. MHH800 and MHH800SQ Deep Vein Thrombosis (DVT) Compression Devices are intended to increase venous blood flow in at risk patients in order to help prevent deep vein thrombosis.

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)]

December 28, 2019

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

Name of Sponsor: B&J Manufacturing Ltd.

Address: Room 701 & 101, Building 24, Block B, Yuanshan Industrial Zone, Shangcun Community, Gongming Street, Guangming District, Shenzhen, 518106 China

Contact Name: Billy Yu

Telephone No.: +86-0755-88210239

Fax No.: +86-0755-88210289

Email Address: yl_billy@126.com

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

Trade Name/Model: B&J DVT Compression Devices MHH800/MHH800SQ

Common Name: MHH800/MHH800SQ DVT Pumps

Classification Name: Sleeve, Limb, Compressible

Regulation Number: 21 CFR 870.5800

Product code: JOW

Classification Panel: Cardiovascular

Device Class: II

4. Identification of Predicate Device(s) [21 CFR 807.92(a) (3)]

The identified predicates within this submission are as follows:
Caremed Supply, Inc., VESOFLOW PLUS DVT Compression Devices, IPCS/SQS have been cleared by FDA through 510(k) No. K141064 (Decision Date - December 4, 2014).

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

The Deep Vein Thrombosis (DVT) Pumps MHH800 and MHH800SQ are external pneumatic compression (EPC) devices that aid in the prevention of DVT from a potentially life threatening condition which can lead to pulmonary embolism. MHH800 and MHH800SQ are non-invasive mechanical prophylactic devices. The devices function as secondary pumps to propel venous blood for patients whose deep veins thrombosis must be prevented after surgeries in Orthopaedics etc. Additionally, the devices are reusable and can be used for more than one patient within its lifecycle.

Model variations are distinguished by characters. MHH800 is without SQ, so the device means an intermittent pneumatic compression pump. MHH800SQ is with SQ, so the device means a sequential pneumatic compression pump.

The two devices separately consist of an air pump and a soft pliable compression garment(s) for the foot, calf or thigh. For MHH800, the controller supplies compression on a preset timing cycle (12 seconds inflation and maintenance followed by 48 seconds of deflation) at a suggested pressure setting of 40 mmHg for the Leg and 120mmHg for the Foot. For MHH800SQ, the controller supplies compression on a preset timing cycle (12 seconds inflation followed by 48 seconds of deflation) at a suggested pressure setting, 45mmHg in the 1st chamber, 40 mmHg in the 2nd chamber and 30mmHg in the 3rd chamber for the Leg and 120mmHg for the Foot. The pressure in the garments is transferred to the extremity, augmenting venous blood flow when the leg is compressed, reducing stasis. This process also stimulates fibrinolysis; thus, reducing the risk of early clot formation.

The DVT pumps produce automatically timed cycles of compressed air. This compressed air forces blood out of the deep veins, helping to prevent slowed or stopped blood flow. Bursts of air are delivered to the specially designed garments wrapped around extremities. This air helps to move blood out of the deep veins and reduce the risk of developing DVT. Garments are lined with tricot fabric to help reduce heat and perspiration.

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

The B&J Manufacturing Ltd. MHH800 and MHH800SQ Deep Vein Thrombosis (DVT) Compression Devices are intended to increase venous blood flow in at risk patients in order to help prevent deep vein thrombosis.

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

MHH800 DVT Pump

General Specification:	
Model No.	MHH800
Size	6.5” (L) x 7.0” (W) x 12.8” (H)
Weight	2.1 kg
Pressure Range	Calf/Thigh Garment: 40mmHg +10/-5mmHg
	Foot Garment: 120mmHg +10/-5mmHg
Input Rating	AC 100V-240V 50/60Hz 1A
Fuse Rating	1A or T1AH 250V
Classification	Class Ⅰ Type BF Not AP or AGP type 
Humidity	Operation: 30% to 75 %
	Storage & Transportation: 30% to 75%
Air pressure	75 - 106KPA
Temperature	Operation: 15°- 35° C
	Storage & Transportation: 5 - 60° C
Cycle Time	Inflation 12 seconds +/- 10%
	Deflation 48 seconds +/- 10%
Applied Part	Garments and Air Tube (100% latex free)
Battery	Battery pack: 4 x series Li-ion battery cell
	Battery pack capacity: 2800mAh (Nominal), 2750mAh (minimum)
	Nominal voltage: 14.8V
	Temperature: Operation 15° ~ 35°C Storage 5° ~ 60°C

Garment for the DVT Pump:			
Model Name	Description		Circumference
MHH801P	Pediatric	Latex Free Calf Garment (Pair)	Up to 14’’
MHH801M	Medium	Latex Free Calf Garment (Pair)	Up to 18’’
MHH801L	Large	Latex Free Calf Garment (Pair)	Up to 24’’
MHH801B	Extra Large	Latex Free Calf Garment (Pair)	Up to 32’’
MHH820M	Medium	Latex Free Foot Garment (Pair)	Up to 13’’
MHH820L	Large	Latex Free Foot Garment (Pair)	Up to 16’’
MHH830S	Small	Latex Free Thigh Garment (Pair)	Up to 22’’
MHH830M	Medium	Latex Free Thigh Garment (Pair)	Up to 29’’
MHH830L	Large	Latex Free Thigh Garment (Pair)	Up to 36’’
MHH830B	Extra Large	Latex Free Thigh Garment (Pair)	Up to 42’’

Air Hose Extension for the DVT Pump:	
810	Air hose extension of 59” (Pair)
810L	Air hose extension of 59” (Pair)

MHH800SQ DVT Pump

General Specification:			
Model No.	MHH800SQ		
Size	6.5” (L) x 7.0” (W) x 12.8” (H)		
Weight	2.58 kg		
Pressure Range	Calf/Thigh Garment: 45/40/30mmHg +10/-5mmHg		
	Foot Garment: 120mmHg +10/-5mmHg		
Input Rating	AC 100V-240V 50/60Hz		
Fuse Rating	1A or T1AH 250V		
Classification	Class Ⅰ Type BF Not AP or AGP type 		
Humidity	Operation: 30% to 75 %		
	Storage & Transportation: 30% to 75%		
Air pressure	75 - 106KPA		
Temperature	Operation: 15°- 35° C		
	Storage & Transportation: 5 - 60° C		
Cycle Time	Inflation 12 seconds +/- 10%		
	Deflation 48 seconds +/- 10%		
Applied Part	Garments and Air Tube (100% latex free)		
Battery	Battery pack: 4 x series Li-ion battery cell		
	Battery pack capacity: 2800mAh (Nominal), 2750mAh (minimum)		
	Nominal voltage: 14.4V		
	Temperature: Operation 15° ~ 35°C Storage 5° ~ 60°C		
Garment for the DVT Pump:			
Model Name	Description		Circumference
MHH801SSQ	Small	Latex Free Calf Garment (Pair)	Up to 14’’
MHH801MSQ	Medium	Latex Free Calf Garment (Pair)	Up to 18’’
MHH801LSQ	Large	Latex Free Calf Garment (Pair)	Up to 24’’
MHH801BSQ	Extra Large	Latex Free Calf Garment (Pair)	Up to 32’’
MHH820MSQ	Medium	Latex Free Foot Garment (Pair)	Up to 13’’
MHH820LSQ	Large	Latex Free Foot Garment (Pair)	Up to 16’’
MHH830SSQ	Small	Latex Free Thigh Garment (Pair)	Up to 22’’
MHH830MSQ	Medium	Latex Free Thigh Garment (Pair)	Up to 29’’
MHH830LSQ	Large	Latex Free Thigh Garment (Pair)	Up to 36’’
MHH830BSQ	Extra Large	Latex Free Thigh Garment (Pair)	Up to 42’’
Air Hose Extension for the DVT Pump:			
810SQ	Air hose extension of 59” (Pair)		
810LSQ	Air hose extension of 59” (Pair)		

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

8.1 Intended uses:

Table 1 Intended Use Comparison

ID	Comparison Item	Proposed Device B&J DVT Compression Devices (MHH800/MHH800SQ)	Predicate Device VESOFLOW PLUS DVT Compression Devices (IPCS/SQS)
1	**510(K) No.**	K200154	K141064
2	**Intended Use**	The B&J Manufacturing Ltd. MHH800 and MHH800SQ Deep Vein Thrombosis (DVT) Compression Devices are intended to increase venous blood flow in at risk patients in order to help prevent deep vein thrombosis.	The Caremed Supply Inc. VESOFLOW® PLUS SQS and IPCS Deep Vein Thrombosis (DVT) Compression Devices are intended to increase venous blood flow in at risk patients in order to help prevent deep vein thrombosis.
3	**Type of use**	Prescription Use	Prescription Use
4	**Single use?**	Reusable(note)	Single use

Note:

The proposed devices can be reusable since their cleaning and disinfection have been validated according to Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff at https://www.fda.gov/media/80265/download and Labeling and Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 at https://www.cdc.gov/infectioncontrol/guidelines/disinfection/.

8.2 Comparison table

Table 2 General Comparison between MHH800 and VESOFLOW®PLUS IPCS

ID	Comparison Item	Proposed Device B&J DVT Compression Device (MHH800)	Predicate Device VESOFLOW PLUS DVT Compression Device (IPCS)	Explanation of Difference
4	**General Specification**			
4.1	Size	6.5”x7.0”x12.8”	7.54”x5.12”x7.95”	Different but does not raise any new issue of substantial equivalence
4.2	Weight	2.1kg	2.8kg	Different but does not raise any new issue of substantial equivalence
4.3	Pressure Range	Calf/Thigh:40; Foot:120	Calf/Thigh:40; Foot:130	Different but same as Reference Device K061814(Calf/ Thigh:40; Foot: 80-120) or K181217(Calf/ Thigh:40; Foot:120)
4.4	Input Rating	AC 100-240V, 50/60Hz	AC 100-240V, 50/60Hz	-
4.5	Fuse Rating	1A or T1AH 250V	1A/250V	-
4.6	Classification	Class Ⅰ Type BF Not AP or AGP type 	Class Ⅰ Type BF Not AP or AGP type 	-
4.7	Operation Humidity	30-75%	30-75%	-

4.8	Storage & Transportation Humidity	30-75%	30-75%	-
4.9	Operation Temperature	15℃-35℃	15℃-35℃	-
4.10	Storage & Transportation Temperature	5℃-60℃	5℃-60℃	-
4.11	Applied Part	Garment and Air Hose	Garment and Air Hose	-
4.12	Applied Mode of Pressure	Intermittent	Intermittent	-
4.13	Number of Chambers in Garment	No	No	-
4.14	Inflation time per chamber (Calf/Thigh)	12 seconds	12 seconds	-
4.15	Deflation time per chamber (Calf/Thigh)	48 seconds	48 seconds	-
4.16	Inflation time per chamber (Foot)	12 seconds	3 seconds	Different but same as Reference Device K061814 or K181217 (all 12 seconds)
4.17	Deflation time per chamber (Foot)	48 seconds	30 seconds	Different but same as Reference Device K061814 or K181217 (all 48 seconds)
4.18	Pressure Range Calf/Thigh	40mmHg	40mmHg	-

4.19	Pressure Range Foot	120mmHg	130mmHg	Different but same as Reference Device K061814 (Foot: 80-120) or K181217 (Foot: 120)
4.20	Pre-Programmed Controls	Yes	Yes	-
4.21	Battery Pack	Yes	Yes	-
4.22	Garments	100% latex free	100% latex free	-

Table 3 General Comparison between MHH800SQ and VESOFLOW®PLUS SQS

ID	Comparison Item	Proposed Device B&J DVT Compression Device (MHH800SQ)	Predicate Device VESOFLOW PLUS DVT Compression Device (SQS)	Explanation of Difference
5	**General Specification**			
5.1	Size	6.5”x7.0”x12.8”	7.54”x5.12”x7.95”	Different but does not raise any new issue of substantial equivalence
5.2	Weight	2.58kg	2.8kg	Different but does not raise any new issue of substantial equivalence
5.3	Pressure Range	Calf/Thigh: 45, 40 and 30mmHg Foot: 120mmHg	Calf/Thigh: 45, 40 and 30mmHg Foot: 130mmHg	Different but same as Reference Device K061814 (Foot: 80-120) or K181217 (Foot: 120))

5.4	Input Rating	AC 100-240V, 50/60Hz	AC 100-240V, 50/60Hz	-
5.5	Fuse Rating	1A or T1AH 250V	1A/250V	-
5.6	Classification	Class Ⅰ Type BF Not AP or AGP type 	Class Ⅰ Type BF Not AP or AGP type 	-
5.7	Operation Humidity	30-75%	30-75%	-
5.8	Storage & Transportation Humidity	30-75%	30-75%	-
5.9	Operation Temperature	15℃-35℃	15℃-35℃	-
5.10	Storage & Transportation Temperature	5℃-60℃	5℃-60℃	-
5.11	Applied Part	Garment and Air Hose	Garment and Air Hose	-
5.12	Applied Mode of Pressure	Sequential	Sequential	-
5.13	Number of Chambers in Garment	3	3	-
5.14	Inflation time per chamber	12 seconds	12 seconds	-
5.15	Deflation time per chamber	48 seconds	48 seconds	-
5.16	Pressure sequence calf/thigh	45, 40 and 30 mmHg	45, 40 and 30 mmHg	-
5.17	Pressure range calf/thigh	45, 40 and 30 mmHg	45, 40 and 30 mmHg	-

5.18	Pressure Range Foot	120mmHg	130mmHg	Different but same as Reference Device K061814 (Foot: 80-120) or K181217 (Foot: 120)
5.19	Pre-Programmed Controls	Yes	Yes	-
5.20	Battery Pack	Yes	Yes	-
5.21	Garments	100% latex free	100% latex free	-

It is clear that the technological characteristics differences discussed above do not affect the safety and the effectiveness of the MHH800 and MHH800SQ.

8.3 Non-clinical Testing

The following safety and performance tests were conducted to assess MHH800 and MHH800SQ DVT compression devices.

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

All the test results demonstrate MHH800 and MHH800SQ DVD compression devices meet the requirements of their predefined acceptance criteria and intended uses.

No clinical testing was used to support the decision of safety and effectiveness.

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 MHH800 and MHH800SQ is totally same as that of the predicate devices.
- The technological characteristics differences between MHH800 and IPCS, and between MHH800SQ and SQS do not affect the safety and effectiveness, no new risk is raised.
- Demonstrated by the safety and performance tests, the characteristics of MHH800 and MHH800SQ are equivalent to those of the predicate devices.