September 18, 2020

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

Re: K201547
Trade/Device Name: B&J DVT Foot Garments, Models 820 Series
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: August 15, 2020
Received: August 21, 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)*

K201547

Device Name

B&J DVT Foot Garments, Models 820 Series

Indications for Use *(Describe)*

The B&J DVT Foot Garments, Models 820 Series are external pneumatic compression devices intended to lower the risk of deep vein thrombosis (DVT) and resulting pulmonary embolism (PE) in patients who may be at risk for thrombosis formation.

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)]

June 20, 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 DVT Foot Garments, Models 820 Series

Common Name: DVT Foot Garments 820 Series

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:
The B&J DVT Foot Garments, Models 820 Series are substantially equivalent to devices, Foot Garment of VasoPress Reprocessed DVT Garment (K112838 decided on 11/10/2011) in commercial distribution by Compression Therapy Concepts, Inc. 35 James Way Eatontown, NJ 07724-2272.

The identified reference devices within this submission are as follows:
Compression Therapy Concepts, Inc., VasoPress DVT System, Pump Model VP500D has been cleared by FDA through 510(k) No. K061814 (Decision Date - November 30, 2006).
Caremed Supply, Inc., VesoFlow Lite DVT Compression Device has been cleared by FDA through 510(k) No. K181217 (Decision Date - August 5, 2018).

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

The 820 series of DVT foot garments are compression devices. When the devices are attached to a pump system, they provide sequentially gradient pressure to a patient foot for the prevention of deep vein thrombosis (DVT). When the compression sleeve is inflated, the veins collapse which forces blood to move upward toward the heart. After compression is complete, the sleeves deflate which allows the veins to reopen and bring oxygenated blood to the foot.

820 series includes 820M, 820L, 820MSQ, 820LSQ. Model variations are distinguished by characters. 820 means foot. M means medium size; L means large size. No SQ means intermittent devices; SQ means sequential devices. For example, 820MSQ means the foot garment is with medium size, and used for a sequential pump.

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

The B&J DVT Foot Garments, Models 820 Series are external pneumatic compression devices intended to lower the risk of deep vein thrombosis (DVT) and resulting pulmonary embolism (PE) in patients who may be at risk for thrombosis formation.

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

820 Series

Series	Model	Size	Description	Type	Materials
820 Series (DVT Prophylaxis Garment For Foot)	820M	13"	Foot Garment, Medium	Intermittent	(nylon loop, polyurethane foam, polyester tricot, TPU film, PVC tube, nylon velcro, polyester & cotton binding, nylon thread, polyester loop, TPU connector) For single air chamber, air cannot be filled by gradient.
	820L	16"	Foot Garment, Large		
	820MSQ	13"	Foot Garment, Medium	Sequential	
	820LSQ	16"	Foot Garment, Large		

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

8.1 Intended use:

Table 1 Intended Use Comparison

ID	Comparison Item	Proposed Device DVT Foot Garments (820 Series)	Predicate Device VasoPress Reprocessed DVT Garment (Foot)
1	**510(K) No.**	To be assigned	K112838
2	**Intended Use**	The B&J DVT Foot Garments, Models 820 Series are external pneumatic compression devices intended to lower the risk of deep vein thrombosis (DVT) and resulting pulmonary embolism (PE) in patients who may be at risk for thrombosis formation.	The DVT Garment is an external pneumatic compression device intended to lower the risk of deep vein thrombosis (DVT) and resulting pulmonary embolism (PE) in patients who may be at risk for thrombosis formation.
3	**Type of use**	Prescription Use	Prescription Use

8.2 Comparison table

Table 2 General Comparison between 820 Series and the predicated devices

ID	Comparison Item	Proposed Device DVT Foot Garments (820 Series)				Predicate Devices Vaso Press DVT Foot Garments (Reprocessed DVT Foot Garment)				Explanation of Difference
1	Model	820M	820L	820MSQ	820LSQ	Reprocessed DVT Foot Garment	Reprocessed DVT Foot Garment	Reprocessed DVT Foot Garment	Reprocessed DVT Foot Garment	The Model difference doesn't affect the substantial equivalence with the predicate.
2	Size	13"	16"	13"	16"	13"	16"	13"	16"	Same
3	Type	Foot Garment, Medium	Foot Garment, Large	Foot Garment, Medium	Foot Garment, Large	Foot Garment, Medium	Foot Garment, Large	Foot Garment, Medium	Foot Garment, Large	Same
4	Material	nylon loop, polyurethane foam, polyester tricot, TPU film, PVC tube, nylon velcro, polyester & cotton binding, nylon thread, polyester loop, TPU connector				nylon loop, polyurethane foam, polyester tricot, TPU film, PVC tube, nylon velcro, polyester & cotton binding, nylon thread, TPU connector				According to the polyester tricot, the polyester loop doesn't affect the substantial equivalence with the predicate.

5	Inflation/deflation cycle times	12 seconds/48seconds	12 seconds/48seconds	12 seconds/48seconds	Same
6	Pressure ranges	120mmHg+10/-5mmHg	120mmHg+10/-5mmHg	80mmHg+/-10%	Different but same as Reference Device K061814 (Foot: 80-120) or K181217 (Foot: 120)
7	Sequencing	Intermittent	Sequential	Intermittent	For 820 without SQ, the sequencing is the same as that of the predicate. For 820 with SQ, the sequencing is different with that of the predicate, but the 820 with SQ, and the predicate are independently used with their specific pumps, which doesn't affect the substantial equivalence with the predicate according to the performance test.

It is clear that the technological characteristics differences discussed above do not affect the substantial equivalence of 820 series with their predicates.

8.3 Non-clinical Testing

The following safety and performance tests were conducted to assess 820 series of garments.

- Biocompatibility
- Performance
  - Bladder burst
  - Leak test
  - Pressure cyclic test with the B&J pneumatic pumps

All the test results demonstrate 820 series of foot garments meet the requirements of its predefined acceptance criteria and intended use.

No clinical testing was used to support the decision of substantial equivalence.

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 820 series is identical to that of the predicate devices.
- The technological characteristic differences between 820 series and the predicate devices do not affect the substantial equivalence, so no new risk is raised.
- Demonstrated by the safety and performance tests, the characteristics of 820 series are substantially equivalent to those of the predicate devices.