September 19, 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: K201532
Trade/Device Name: B&J DVT Calf/Thigh Garments, Models 801/830 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)*

K201532

Device Name

B&J DVT Calf/Thigh Garments, Models 801/830 Series

Indications for Use *(Describe)*

The B&J DVT Calf/Thigh Garments, Models 801/830 Series are designed to increase venous blood flow in at risk patients in order to help lower the risk of Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE).

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)]

March 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 DVT Calf/Thigh Garments, Models 801/830 Series

Common Name: DVT Calf/Thigh Garments 801/830 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 Device(s) [21 CFR 807.92(a) (3)]

Primary Predicate

K061967 - VasoQuential, Model VP530

Reference Device

K991038 - VasoPress DVT Calf Garments VP 501

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

The 801/830 series of DVT calf/thigh garments are compression devices. When the devices are attached to a pump system, they provide intermittent, sequentially gradient pressure to a patient calf/thigh 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 calf or thigh.

801 series includes 801M, 801L, 801B, 801P, 801MSQ, 801LSQ, 801BSQ and 801PSQ. 830 series includes 830M, 830L, 830B, 830S, 830MSQ, 830LSQ, 830BSQ and 830SSQ. Model variations are distinguished by characters. 801 means calf; 830 means thigh. M means medium size; L means large size; B means extra large size; P or S means small size. SQ means sequential; no SQ means intermittent. For example, 801MSQ means the calf garment is with medium size, and used for a sequential pump.

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

The B&J DVT Calf/Thigh Garments, Models 801/830 Series are designed to increase venous blood flow in at risk patients in order to help lower the risk of Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE).

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

801/830 Series

Series	Size Range	Model	Size	Description	Type (materials)
801 Series (DVT Prophylaxis Garment For Calf)	14"-32"	801M	18"	Calf Garment, Medium	Intermittent (materials: nylon loop, polyster loop, polyurethane foam, polyster tricot, PVC film, PVC tube, nylon velcro, polyster & cotton binding, nylon thread) For single air chamber, air cannot be filled by gradient.
		801L	24"	Calf Garment, Large	
		801B	32"	Calf Garment, Extra Large	
		801P	14"	Calf Garment, Small	
		801MSQ	18"	Calf Garment, Medium	Sequential (materials:nylon loop, polyurethane foam, polyster tricot, TPU film, PVC tube, nylon velcro, polyster & cotton binding, nylon thread) For three air chambers, air can be filled by gradient.
		801LSQ	24"	Calf Garment, Large	
		801BSQ	32"	Calf Garment, Extra Large	
		801PSQ	14"	Calf Garment, Small	
830 Series (DVT Prophylaxis Garment For Thigh)	14"-42"	830M	29"	Thigh Garment, Medium	Intermittent (materials: nylon loop, polyster loop, polyurethane foam, polyster tricot, PVC film, PVC tube, nylon velcro, polyster & cotton binding, nylon thread) For single air chamber, air cannot be filled by gradient.
		830L	36"	Thigh Garment, Large	
		830B	42"	Thigh Garment, Extra Large	
		830S	14"	Thigh Garment, Small	
		830MSQ	29"	Thigh Garment, Medium	Sequential (materials:nylon loop, polyurethane foam, polyster tricot, TPU film, PVC tube, nylon velcro, polyster & cotton binding, nylon thread) For three air chambers, air can be filled by gradient.
		830LSQ	36"	Thigh Garment, Large	
		830BSQ	42"	Thigh Garment, Extra Large	
		830SSQ	14"	Thigh Garment, Small	

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

8.1 Intended use:

Table 1 Intended Use Comparison between 801 Series and VP501

ID	Comparison Item	Proposed Device DVT Calf Garments (801 Series)	Predicate Device Vaso Press Calf Garments (VP501)
1	**510(K) No.**	To be assigned	K991038
2	**Intended Use**	The B&J DVT Calf/Thigh Garments, Models 801/830 Series are designed to increase venous blood flow in at risk patients in order to help lower the risk of Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE).	The Vaso Press system is an external pneumatic compression system intended to lower the risk of deep vein thrombosis (DVT) in patients whom may be at risk.
3	**Type of use**	Prescription Use	Prescription Use

Table 2 Intended Use Comparison between 830 Series and VP530

ID	Comparison Item	Proposed Device DVT Thigh Garments (830 Series)	Predicate Device VasoQuential Thigh Garments (VP530)
1	**510(K) No.**	To be assigned	K061967
2	**Intended Use**	The B&J DVT Calf/Thigh Garments, Models 801/830 Series are designed to increase venous blood flow in at risk patients in order to help lower the risk of Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE).	The VasoQuential is designed to increase venous blood flow in at risk patients in order to help prevent Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE).
3	**Type of use**	Prescription Use	Prescription Use

8.2 Comparison table

Table 3 General Comparison between 801 Series and VP501

ID	Comparison Item	Proposed Device DVT Calf Garments (801 Series)								Predicate Device Vaso Press Calf Garments (VP501)								Explanation of Difference
1	Model	801M	801L	801B	801P	801MSQ	801LSQ	801BSQ	801PSQ	VP501M	VP501L	VP501B	VP501P	VP501M	VP501L	VP501B	VP501P	The Model difference doesn't affect the substantial equivalence with the predicate.
2	Size	18"	24"	32"	14"	18"	24"	32"	14"	18"	24"	32"	14"	18"	24"	32"	14"	Same
3	Type	Calf Garment, Medium	Calf Garment, Large	Calf Garment, Extra Large	Calf Garment, Small	Calf Garment, Medium	Calf Garment, Large	Calf Garment, Extra Large	Calf Garment, Small	Calf Garment, Medium	Calf Garment, Large	Calf Garment, Extra Large	Calf Garment, Small	Calf Garment, Medium	Calf Garment, Large	Calf Garment, Extra Large	Calf Garment, Small	Same
4	Material	nylon loop, polyster loop, polyurethane foam, polyster tricot, PVC film, PVC tube, nylon velcro, polyster & cotton binding, nylon thread				nylon loop, polyurethane foam, polyster tricot, TPU film, PVC tube, nylon velcro, polyster & cotton binding, nylon thread				nylon loop, polyster loop, polyurethane foam, polyster tricot, PVC film, PVC tube, nylon velcro, polyster & cotton binding, nylon thread								For 801 without SQ, the materials are the same as those of the predicate device. For 801 with SQ, no polyster loop and the PVC film is changed to TPU film, which doesn't affect the substantial equivalence with the predicate according to VP520 of K003828.

5	Inflation/deflation cycle times	12 seconds/48seconds	12 seconds/48seconds	12 seconds/48seconds	Same
6	Pressure ranges	40mmHg	45, 40 and 30 mmHg	40mmHg	For 801 without SQ, the pressure range is same as that of the predicate. For 801 with SQ, the pressure range is different but same as Reference Device K061814 VESOFLOW®PLUS SQS (Calf: 45, 40 and 30mmHg)
7	Sequencing	Intermittent	Sequential	Intermittent	For 801 without SQ, the sequencing is the same as that of the predicate. For 801 with SQ, the sequencing is different with that of the predicate, but the 801 with SQ, and the predicate are independently used with their specific pumps, which doesn't the substantial equivalence with the predicate according to the performance test.

Table 4 General Comparison between 830 Series and VP530

ID	Comparison Item	Proposed Device DVT Thigh Garments (830 Series)								Predicate Device Vaso PressThigh Garments (VP530)								Explanation of Difference
1	Model	830M	830L	830B	830S	830MSQ	830LSQ	830BSQ	830SSQ	VP530M	VP530L	VP530M	VP530L	VP530M	VP530L	VP530M	VP530L	The Model difference doesn't affect the substantial equivalence with the predicate.
2	Size	29"	36"	42"	14"	29"	36"	42"	14"	29"	36"	29"	36"	29"	36"	29"	36"	The size difference doesn't affect the substantial equivalence with the predicate.
3	Type	Thigh Garment, Medium	Thigh Garment, Large	Thigh Garment, Extra Large	Thigh Garment, Small	Thigh Garment, Medium	Thigh Garment, Large	Thigh Garment, Extra Large	Thigh Garment, Small	Thigh Garment, Medium	Thigh Garment, Lzarge	Thigh Garment, Medium	Thigh Garment, Large	Thigh Garment, Medium	Thigh Garment, Large	Thigh Garment, Medium	Thigh Garment, Large	The same type and different size don't affect the substantial equivalence with the predicate.
4	Material	nylon loop, polyster loop, polyurethane foam, polyster tricot, PVC film, PVC tube, nylon velcro, polyster & cotton binding, nylon thread				nylon loop, polyurethane foam, polyster tricot, TPU film, PVC tube, nylon velcro, polyster & cotton binding, nylon thread				nylon loop, polyster loop, polyurethane foam, polyster tricot, PVC film, PVC tube, nylon velcro, polyster & cotton binding, nylon thread								For 830 without SQ, the materials are the same as those of the predicate device. For 830 with SQ, no polyster loop and the PVC film is changed to TPU film, which doesn't affect the substantial equivalence with the predicate according to VP520 of K003828.

5	Inflation/deflation cycle times	12 seconds/48seconds	12 seconds/48seconds	12 seconds/48seconds	Same
6	Pressure ranges	40mmHg	45, 40 and 30 mmHg	40mmHg	For 830 without SQ, the pressure range is same as that of the predicate. For 830 with SQ, the pressure range is different but same as Reference Device K061814 VESOFLOW®PLUS SQS (Thigh: 45, 40 and 30mmHg)
7	Sequencing	Intermittent	Sequential	Intermittent	For 830 without SQ, the sequencing is the same as that of the predicate. For 830 with SQ, the sequencing is different with that of the predicate, but the 830 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 801 series and 830 series with their predicates.

8.3 Non-clinical Testing

The following safety and performance tests were conducted to assess 801 series and 830 series garments.

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

All the test results demonstrate 801 series and 830 series 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 801 series and 860 series is identical to that of the predicate devices.
- The technological characteristics differences between 801 and Vaso Press VP501, 830 and Vaso Press VP530 do not affect the substantial equivalence, so no new risk is raised.
- Demonstrated by the safety and performance tests, the characteristics of 801 series and 830 series is substantially equivalent to those of the predicate devices.