January 26, 2021

VASOInnovations, Inc.
℅ Prithul Bom
Regulatory Technology Services
1000 Westgate Drive, Suite 510k
Saint Paul, Minnesota 55114

Re: K203803
Trade/Device Name: VASOBand Vascular Compression Device
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular clamp
Regulatory Class: Class II
Product Code: DXC
Dated: December 23, 2020
Received: December 28, 2020

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Rachel Neubrander
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)*
K203803

Device Name
VASOBandTM Vascular Compression Device

Indications for Use *(Describe)*
The VASOBandTM is a compression device to assist patent hemostasis of the radial artery after a transradial procedure.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

VASOInnovations, Inc. VASOBand™ Vascular Compression Device

I. SUBMITTER

VASOInnovations, Inc.
1260 Huntington Drive, Suite 208
South Pasadena, CA 91030

Contact person: Raj Sardesai, Ph.D., J.D.
Phone: 626-688-2568
Fax: 323-999-7562
Date prepared: October 2, 2020

II. DEVICE

Name of the device: VASOBand™ Vascular Compression Device
Common or usual name: Vascular compression device
Regulation Number: 21 CFR 870.4450
Classification name: Vascular Clamp
Classification Panel: Cardiovascular Surgical Devices
Regulatory Class: II
Product Code: DXC

III. PREDICATE DEVICE

VASOBand™ (K190318)

To the knowledge of the submitter of this 510(k), this predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The VASOBand™ Vascular Compression Device is an external compression device to promote patent radial artery hemostasis after a transradial procedure. The VASOBand™ Vascular Compression Device is an external compression device used on a human arm and provides a means for a healthcare professional to apply external compression proximal to and/or over a catheterization puncture site for the purpose of assisting post-procedure patent hemostasis at a

target vessel's puncture site. Each device is a single-use, sterile, individually pouched inflatable band. The VASOBand™ Vascular Compression Device is available in two different lengths. The strap measures approximately 26 cm or 29 cm in length and is composed of biocompatible multiple-layer PVC film and PVC tubing, and valves made of biocompatible thermoplastics. Hook and loop materials are used to secure the strap in position. Only the biocompatible thermoplastic film comes into contact with broken skin. The user can control the compression applied by the device by introducing or removing air in a bladder of the device.

The proposed device trade name is VASOBand™ Vascular Compression Device ("VASOBand"). A list of VASOBand™ Vascular Compression Device configurations is provided in Table 3.1.

Table 3.1 – VASOBand™ Product List

Model	SKU	Number of Inflatable Bladders	Band Size [Length]
VB-2600-AR	Right	2	26 cm
VB-2900-AR	Right	2	29 cm
VB-2600-AL	Left	2	26 cm
VB-2900-AL	Left	2	29 cm

V. INDICATION FOR USE

The VASOBand™ is a compression device to assist patent hemostasis of the radial artery after a transradial procedure.

This difference in the indications for use between the proposed and predicate devices does not raise different questions of safety and effectiveness.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Characteristics of the proposed device have been evaluated using established scientific methodology such as design verification, biocompatibility testing and clinical testing. No significant differences between the proposed and the predicate device were found that would adversely affect the use of the device, and the differences do not raise any new issues of safety or effectiveness. The differences in the technological characteristics between the proposed and predicate devices are the hook and loop fastener

materials and the welding of the fasteners to the band. VASOInnovations, Inc. believes that any difference in the technological characteristics between the proposed and predicate devices does not raise different questions of safety and effectiveness.

The proposed VASOInnovations VASOBand™ Vascular Compression Device utilizes substantially equivalent performance attributes and safety components as the predicate device. The subject and predicate device are based on the following same technological elements:

• Product Code • Device Classification Name • 21 CFR Regulation Number • Indications for Use (vs. primary predicate) • Principle of Operation • Target Population • Intended User • Anatomical Site • Where Used • Human Factors • Packaged Sterile • Sterile Barrier System • Primary Packaging Barrier • Shelf Carton • Not Re-sterilized • Sterilization Method • Shelf Life • Pouch/Shelf Box Label • Shipper Box Label • Shipping Carton	• Labeling • Biocompatibility Test Results • Method of compression • Clear Adjustable Strap Around Arm • Air injection ports • Air Bladder • Allows Variation in Applied Pressure • Allows Gradual Release of Pressure • Pressure can be adjusted Without Unfastening Strap • Direct Compression • External Compression • Method of Pressure Adjustment • Quick Release Mechanism • Supporting Plastic Insert in Band

The following technological differences exist between the subject and predicate devices:

• Patent hemostasis indication • Instructions For Use • Instructions For Use Material	• Hook material • Loop material • Hook and loop attachment to band (RF welding)

The proposed and predicate devices are identical in appearance and have adjustable bands that surround the arm having an area of the band that compresses the arm over a vascular access site to assist in hemostasis. The differences, as noted above, are the hook and

loop fastener materials and the welding of the fasteners to the band. The hook and loop used in the predicate device were applied to the band solely with adhesive backing. In the proposed device, the hook fastener has changed to nylon (with a corresponding change to the loop fastener of a compatible family). The hook and loop fasteners used in the proposed device are compatible with the RF welding to secure the fasteners to the base band material. No other technological difference exists between the proposed and predicate devices.

The predicate device has a similar indication for use:

> The VASOBand™ is a compression device to assist hemostasis of the radial artery after a transradial procedure.

VII. PERFORMANCE TESTING - BENCH

The manufacturing and material change of the fastener mechanism does not impact the ability of the band to assist patent hemostasis. The following performance testing was performed in support of substantial equivalence based on the minor differences between hook and loop fastener materials and production methods:

Test	Results
Fastener peel force	Pass
Fastener slippage	Pass
Cytotoxicity Study Using the ISO Elution Method	Pass
ISO Guinea Pig Skin Sensitization Study	Pass
ISO Intracutaneous Irritation Study	Pass
USP Rabbit Material-Mediated Pyrogen Study	Pass
ISO Acute Systemic Toxicity Study	Pass

The VASOBand™ Vascular Compression Device met all specified criteria and based on the design verification performance testing. The conclusions drawn from the performance tests demonstrate that the device is as safe, as effective, and performs as well as the legally marketed predicate device.

VIII. PERFORMANCE TESTING - CLINICAL

Clinical performance data is leveraged from publicly available information of a clinical trial conducted by an independent sponsor-

investigator. The following publicly available performance data is provided in support of the indication for patent hemostasis:

- Clinical Study (www.clinicaltrials.gov; NCT04002791) including the study protocol that is available on this website.
- Patel G, Shah S, Patel BA, Patel TM. Randomized C**O**mparison of Isolated Radial Artery Com**P**r**E**ssio**N** Versus **Radial** and Ipsilateral Ulnar Artery Compression in Achieving Radial Artery Patency: The OPEN-Radial Trial, 2020, *J Invasive Cardiol* 32(9):Epub

The VASOBand™ Vascular Compression Device met all specified criteria.

VIII. EQUIVALENCE

The indications for use for the predicate devices are similar to the indications for use for the proposed VASOBand™ Vascular Compression Device. Furthermore, the VASOBand™ Vascular Compression Device has the same intended use, patient population, and anatomical sites as well as similar technological characteristics as the predicate device. The differences in technological characteristics have been analyzed and addressed through performance testing, and clinical testing results support use of VASOBand™ Vascular Compression Device to assist patent hemostasis. Any differences in the technological characteristics between the devices do not raise different questions of safety or effectiveness.

IX. CONCLUSION

The VASOBand™ Vascular Compression Device has the same intended use, patient population, and anatomical sites as well as similar technological characteristics as the predicate devices. The differences in technological characteristics have been analyzed and addressed through testing. As such, the nonclinical and clinical tests demonstrated that the device is as safe, as effective, and performs as well as the predicate device.

X. SUMMARY

The VASOBand™ Vascular Compression Device is as safe, as effective, and performs as well as the predicate device.