October 30, 2020

Medical Ingenuities
% Valerie Defiesta-Ng
Vice President, Regulatory Affairs
Experien Group, LLC
224 Airport Parkway, Suite 250
San Jose, California 95110

Re: K201695
Trade/Device Name: PH Band
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: June 19, 2020
Received: June 22, 2020

Dear Valerie Defiesta-Ng:

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 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)*
K201695

Device Name
PH Band

Indications for Use *(Describe)*
The PH Band is a compression device used to assist 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) Notification K201695

GENERAL INFORMATION [807.92(a)(1)]

Applicant:

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USA
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Contact Person:

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Date Prepared: October 30, 2020

DEVICE INFORMATION [807.92(a)(2)]

Trade Name:

PH Band

Common Name:

Compression Device

Classification Name:

Clamp, Vascular

Classification:

II

Product Code:

DXC

510(k) SUMMARY K201695

PREDICATE DEVICE(S) [807.92(a)(3)]

Medtronic Vascular TRAcelet Compression Device (K162027)

DEVICE DESCRIPTION [807.92(a)(4)]

The PH Band, herein referred to as the "Device," is an compression device consisting of a wrist band (also referred to as the "band"), a syringe, and two finger cots. The Device is used to assist in the hemostasis of the radial artery after a transradial percutaneous procedure.

The Device is similar to the predicate device but differs in that it has been designed to be used in conjunction with an ultrasound doppler system utilizing a flat doppler probe. The PH Band may be used to achieve patent hemostasis when used with the recommended Doppler technology. Located on the Radial Artery Compression Band of the Device is an Access Site Visualization Window used to visualize the hemostasis of the access site. An ultrasound doppler probe is placed immediately distal to the access site and under the Doppler Probe Harnessing band portion of the PH Band. The probe can be viewed and aligned within the access site window. When used with the Doppler probe, the device not only gains hemostasis but allows the physician to confirm patency and confirms antegrade blood flow distal to the access site compression bladder via the ultrasound doppler probe. Use of the doppler system helps guide the physician in applying the appropriate amount of pressure to achieve patent hemostasis and avoid over-compression of the radial artery during wound closure.

INDICATIONS FOR USE [807.92(a)(5)]

The PH Band is a compression device used to assist hemostasis of the radial artery after a transradial procedure.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES [807.92(a)(6)]

The PH Band is similar to the predicate device with respect to the intended use and technological characteristics. Medical Ingenuities performed comprehensive testing on the PH Band, including: nonclinical bench testing to demonstrate that the device met all required specifications and performs as intended, e.g., biocompatibility testing, transit testing, shelf life testing, and a sterilization validation. The testing demonstrated that the technological differences do not raise any different questions of safety and effectiveness from the predicate device.

SUBSTANTIAL EQUIVALENCE

The PH Band and the predicate device, TRAcelet Compression Device (K162027), are substantially equivalent with regard to intended use, performance, and technological characteristics.

The minor differences in the technological characteristics, and indications for use between the subject Device and the primary predicate device have been evaluated and determined to not raise any different questions of safety and effectiveness. As such, the PH Band is substantially equivalent to the TRAcelet Compression Device (K162027). A comparison table summarizing the specifications and features of the PH Band and the predicate device is included in Table 1.

Table 1: Substantial Equivalence Table – Regulatory Information

Device Name	PH Band (Subject Device)	TRAcelet Compression Device (Primary Predicate)	Rationale for Substantial Equivalence
510(k) Number	-	K162027	N/A
Company	Medical Ingenuities	Medtronic Vascular	N/A
Classification	21 CFR§870.4450 (Class II)	21 CFR§870.4450 (Class II)	Same
Product Code	DXC – Clamp, Vascular	DXC – Clamp, Vascular	Same
Indications for Use	The PH Band is a compression device used to assist hemostasis of the radial artery after a transradial procedure.	The compression device is used to assist patent hemostasis of the radial artery after a transradial procedure.	Same
Single Use	Intended for single use only.	Intended for single use only.	Same
Prescription/ Over-the-Counter	Prescription Use	Prescription Use	Same
Components	• Compression Band • Syringe (30mL) • 2 Finger Cots	• Compression Band • Customized Syringe	Similar. The differences in the components do not raise different questions of safety or effectiveness, as demonstrated by performance testing.
Doppler Compatibility	• Designed for use with an ultrasound doppler system and flat doppler probe. • Designed with a secondary strap incorporated to hold the doppler probe in place.	• Does not include a strap to hold a Doppler in place.	These differences do not raise any different questions of safety or effectiveness, as demonstrated by performance testing.

Table 1: Substantial Equivalence Table – Regulatory Information (cont.)

Device Name	PH Band (Subject Device)	TRAcelet Compression Device (Primary Predicate)	Rationale for Substantial Equivalence
Sizing	The PH Band is a Universal Radial Compression Band (Right or Left) that is 30.5cm in length. The Velcro loop side of the band can be cut to fit a smaller wrist by first wrapping the band around the patient's wrist and then cutting off any excess. Up to 10.8cm of length can be cut off the Velcro loop bands.	Band length available in two sizes (19.2cm or 25.2cm).	Similar. The difference in dimensions does not raise different questions of safety or effectiveness, as demonstrated by inspection and performance testing.
Sterility	Radiation (Electron Beam) Sterilized (ISO 11137-1:2006 +A1:2013 and EN ISO 11137-1:2015 to provide a Sterility Assurance Level of 10^{-6}.)	Ethylene Oxide Sterilized (ANSI/AAMI/ISO 11135:1994 to provide a Sterility Assurance Level of 10^{-6}.) Similar to predicate (Terumo Corporation, TR Band device (K070423)).	The difference in sterilization method does not raise different questions of safety or effectiveness, as demonstrated by the sterilization validation.
Nonclinical Bench Testing/In Vitro Bench Testing	• Visual Inspection • Dot Detection • Doppler Compatibility • Bladder Leak • Pressure Decay • Velcro Peel Strength • Velcro Shear Strength • Luer Valve/Tubing Tensile • Bladder Burst	• Effective Strap Length • Syringe to Anti-Lock Cap Tensile • Balloon Rupture • Side-Tube to Balloon Tensile • Side-Tube to Check Valve Tensile • Velcro to Lay Flat Tubing Weld Tensile • Rivet Joint Tensile Regular • Dial Removal Torque • Dial to Threaded Window Shear Strength • Initial Balloon Inflations Pressure • Balloon Internal Pressure Over Time • Dial Torque • Dial Lock Disengagement Force	Similar. The differences in testing performed do not raise different questions of safety or effectiveness.

Table 1: Substantial Equivalence Table – Regulatory Information (cont.)

Device Name	PH Band (Subject Device)	TRAcelet Compression Device (Primary Predicate)	Rationale for Substantial Equivalence
Biocompatibility Testing	• Cytotoxicity Testing • Sensitization Testing • Intracutaneous Reactivity Testing • Acute Systemic Toxicity Testing • Material Medicated Pyrogenicity Testing	• Cytotoxicity Testing • Sensitization Testing • Intracutaneous Reactivity Testing • Acute Systemic Toxicity Testing	Similar. The differences in testing performed do not raise different questions of safety or effectiveness. All testing was performed in accordance with ISO 10993-1.

PERFORMANCE DATA [807.92(b)]

All necessary bench testing was conducted on the PH Band to support a determination of substantial equivalence to the predicate device.

[807.92(b)(1)] Nonclinical Testing Summary:

Testing included:

- Nonclinical Bench Testing
  - Visual Inspection
  - Dot Detection Test
  - Doppler Compatibility
  - Bladder Leak Test
  - Pressure Decay Test
  - Velcro Peel/Shear Strength Test
  - Luer Valve/Tubing Tensile Test
- Sterilization Validation
- Biocompatibility Testing
- Transit Testing
- Shelf Life Validation
- Bladder Burst Testing

The collective results of the nonclinical testing demonstrate that the materials chosen, the manufacturing processes, and design of the PH Band meet the established specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that the PH Band does not raise new or different questions of safety or effectiveness when compared to the predicate device.

[807.92(b)(2)] Clinical Testing Summary:

Clinical data was not required to demonstrate substantial equivalence.

CONCLUSIONS [807.92(b)(3)]

Extensive performance testing has been performed on the PH Band to evaluate the overall performance of the device. The collective results confirm that the Device meets its specifications and exhibits the required medical and functional characteristics for its intended use to compress/close and assist in hemostasis of the radial artery and as such, is substantially equivalent to the predicate device.