DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 21, 2016

Medtronic Vascular
Ms. Colleen Mullins
Principle Regulatory Affairs Specialist
37A Cherry Hill Drive
Danvers, Massachusetts 01923

Re: K162027
Trade/Device Name: TRAcelet™ Compression Device
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: September 8, 2016
Received: September 9, 2016

Dear Ms. Mullins:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

for 

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162027

Device Name
TRAcelet™ Compression Device

Indications for Use *(Describe)*
The compression device is used 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

Submitter: Medtronic Vascular
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Date Prepared: October 13, 2016

Trade Name(s): TRAcelet™ Compression Device

Common Name: Compression Device

Classification Name: Vascular Clamp

Predicate Device:

Device Name	Manufacturer	510(k) clearance #
TR Band	Terumo	K070423

Device Description: The TRAcelet™ compression device consists of a closure band and customized syringe. The device is used to assist in the hemostasis of the radial artery after a transradial percutaneous procedure

Indications for Use: The TRAcelet™ compression device is used to assist patent hemostasis of the radial artery after a transradial procedure.

Summary of Technological Characteristics: Medtronic's TRAcelet™ compression device consists of a closure band and customized syringe. There are two different size closure bands regular (19.2cm) and large (25.2cm) comprised of the following technological characteristics:

- Dial
- Frame

- Dial-Threaded Window Assembly
- Balloon Assembly
- Air Injection Port (Luer Check Valve Assembly
- Strap Assembly

Comparison to the predicate devices:

The following information outlines the differences and similarities between the subject device and the predicate device:

- Similar Intended Use
- Similar Device Design Component/ Construction
- Different device materials
- Similar packaging type
- Similar sterilization technology/ method

Medtronic's TRAcelet™ is substantially equivalent to the predicate device based on similarities in intended use and technological characteristics. The testing performed to assess safety and effectiveness of the TRAcelet™ demonstrates that the technological differences do not raise any new concerns of safety and effectiveness.

Summary of Non-clinical Data:

The following non-clinical testing was performed to assess safety and effectiveness of Medtronic's TRAcelet™

1. **Design Verification Testing/ In-vitro bench testing**:

Design Verification (DV) testing was completed to demonstrate that the TRAcelet™ meets the key safety and effectiveness requirements for its intended clinical use. The Design Verification Testing included *in-vitro* bench testing on finished devices which were representative of commercial device and included:

- 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 flatTubing Weld Tensile
- Rivet Joint Tensile Regular

- Dial Removal Torque
- Dial to Threaded Window Shear Strength
- Initial Balloon Inflation Pressure
- Balloon Internal Pressure Over Time
- Dial Torque
- Dial Lock Disengagement Force

2. Biocompatibility Testing:

The following Biocompatibility Testing was completed on the TRAcelet™ in compliance with the requirements of ISO 10993-1: 2009/ Cor 1: 2010- *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*.

- Cytotoxicity testing
- Sensitization testing
- Intracutaneous reactivity testing
- Acute systemic toxicity testing

No new safety or effectiveness issues were raised during the testing. The bench testing qualification and biocompatibility testing demonstrated that Medtronic's TRAcelet™ is safe and effective for its intended clinical use.

Summary of Clinical Data: No clinical investigation was performed on the subject device (TRAcelet™).

Conclusion from Data: The data provided in this 510(k) premarket notification demonstrated that the subject device is substantially equivalent to the predicate device.