



November 10, 2015

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Terumo Medical Corporation
Liang Lu
Senior Regulatory Affairs Specialist
950 Elkton Blvd
Elkton, Maryland 21921

Re: K152525

Trade/Device Name: TR Band Radial Compression Device
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: September 2, 2015
Received: September 3, 2015

Dear Mr. Lu:

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 and Part 809); 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 and Part 809), 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 yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman". The signature is written in a cursive style and is positioned above the typed name.

for
Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K152525

Device Name

TR BAND® Radial Compression Device

Indications for Use (Describe)

The TR BAND® Radial Compression Device is a compression device 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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SECTION 5 – 510(K) SUMMARY

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510(K) SUMMARY

A. SUBMITTER INFORMATION (807.92(a)(1))

Prepared by:

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Prepared for: *Owner/Operator*

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Manufacturer (510(k) Applicant)

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Date prepared: November 3, 2015

B. DEVICE NAME (807.92(a)(2))

Proprietary Name: TR BAND® Radial Compression Device
Common Name: Radial compression device
Classification Name: Vascular clamp
Classification Panel: Cardiovascular
Regulation: 21 CFR 870.4450
Product Code: DXC
Classification: Class II

C. PREDICATE DEVICE (807.92(a)(3))

The legally marketed device(s) to which substantial equivalence is claimed is:
K070423 – TR Band™, manufactured by Terumo Corporation, Japan

D. DEVICE DESCRIPTION (807.92(a)(4))

The TR BAND® Radial Compression Device is a tourniquet style device consisting of a plastic belt with hook and loop adjustable fastener on each end, two compression balloons, and an injection port. The device also contains a TR Band Inflator.

After a Transradial catheterization procedure, the TR Band is placed around the patient's wrist and the hook and loop strap is connected. Once the introducer sheath is removed from the patient's wrist, pressure is applied to the patient's access site by

inflating the compression balloons of the TR Band. Both compression balloons are filled at the same time while air is being introduced through the air injection port.

The balloons are inflated when air is injected into the air injection port by the TR Band Inflator. The TR Band inflator is a specially designed syringe for use only with the TR Band. A valve on the air injection port assures that the air remains within the compression balloons. The volume of air can be reduced or increased by use of the TR Band Inflator (20ml syringe). This allows the physician to make fine adjustments to the pressure in the TR Band.

With the two compression balloons (large and small) the pressure is applied for efficient compression for hemostasis. The belt also has a support plate over the two compression balloons to assure that the balloons and belt conform to the contour of the wrist. The belt and compression balloons are made of clear plastic which allows the physician to view the access site during the hemostasis process.

The TR Band is a disposable device intended for single use only. This device is individually packaged and sterilized by ethylene oxide gas.

E. INDICATIONS FOR USE (807.92(a)(5))

The TR BAND® Radial Compression Device is a compression device to assist hemostasis of the radial artery after a transradial procedure.

Note: The indications for use are identical to the predicate device.

F. SUBSTANTIAL EQUIVALENCE COMPARISON (807.92(a)(6))

The TR BAND® Radial Compression Device, subject of this 510(k), is substantially equivalent in its intended use/indications for use, technology/principal of operation, materials, and performance to the TR Band, manufactured by Terumo Corporation.



A comparison of the technological characteristics is summarized on the table below.

Table 5.4: Summary of Substantial Equivalence

Device Characteristic	Predicate: TR Band, K070423	New Device: TR BAND® Radial Compression Device
Manufacturer	Terumo Corporation	Terumo Medical Corporation
Intended Use / Indications for Use	The TR Band™ is a compression device to assist hemostasis of the radial artery after a transradial procedure.	Same
Operation Principle	Operated manually or by a manual process; Pneumatic compression balloons are filled to apply pressure to the access site	Same
Design/ Construction	A plastic belt with hook and loop adjustable fastener on each end, two compression balloons, and an injection port. The device also contains a TR Band Inflator and an Air Volume Regulator	Same design and construction. (The only difference is that the TR Band Air Volume Regulator is not being made available for the new device)
Package	<ul style="list-style-type: none"> • Unit Pouch • Shelf Box • Shipping Carton 	<ul style="list-style-type: none"> • Lidded tray • Shelf Box • Shipping Carton
Specifications	Length of band (belt): Large TR Band is 24 cm Large TR Band is 29cm	Same
Sterilization	Ethylene Oxide (validated in accordance with ANSI / AAMI / ISO 11135-1 to achieve SAL 10 ⁻⁶)	Same
Shelf life	30 months	12 months
Disposable Single Use	Yes	Same

The materials of the proposed TR BAND® Radial Compression Device are identical to those of the predicate device.

G. NON CLINICAL TESTS (807.92(b)(1))

Performance

Performance testing was conducted to demonstrate substantial equivalence to the predicate device, verify conformity to applicable external and internal standards, and verify that aging does not affect the TR Band Radial Compression Device. All testing met acceptance criteria. **Tables 5.4** below provide a list of the performance tests that were performed on the proposed TR BAND® Radial Compression Device.

Table 5.4: Summary of Performance Testing

Standard Designation	Standard Name
ISO 10993-1:2009 Cor. 1:2010	Biological Evaluation of Medical Devices Part 1: Evaluation and testing
ISO 10993-5: 2009	Biological Evaluation of Medical Devices- Part 5: Tests for in vitro cytotoxicity
ISO 10993-7:2008 Cor.1:2009	Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals
ISO 10993-10: 2010	Biological Evaluation of Medical Devices- Part 10: Tests for irritation and skin sensitization
ISO 10993-11: 2006	Biological Evaluation of Medical Devices- Part 11: Tests for systemic toxicity
ISO 10993-12: 2012	Biological Evaluation of Medical Devices- Part 12: Sample preparation and reference materials
USP 38 <85>	Bacterial Endotoxins Test. (Sterility)
USP 38 <151>	Pyrogenicity Test (USP Rabbit Test)
ISO 11135: 2014	Sterilization Of Health-Care Products - Ethylene Oxide - Requirements For The Development, Validation And Routine Control Of A Sterilization Process For Medical Devices. (Sterility)
USP 38 <661>	Containers- Plastics, Physicochemical Tests
ASTM F-1980-07	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.
ASTM D4169-14	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM F1929-12	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration

Standard Designation	Standard Name
ISO 11607-1:2006/A1:2014	Packaging For Terminally Sterilized Medical Devices - Part 1: Requirements For Materials, Sterile Barrier Systems And Packaging Systems.
ASTM F88/F88M:09	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM F2825-10	Standard Practice for Climatic Stressing of Packaging Systems for Single Parcel Delivery
ISO 14971:2007/(R)2010	Medical devices - Application of risk management to medical devices
Internal Standards	<ul style="list-style-type: none">- Visual/Appearance- Dimensional- Functional performance

Preclinical testing, including dimensional verification, device bond strength, balloon inflation and deflation testing, and hemostasis valve testing was conducted to confirm the device would function as intended. Additionally, dye leak testing was performed in accordance with ASTM F1929-12 on the modified packaging. All testing met acceptance criteria.

Based on the results of the performance testing, the proposed TMC TR Band is substantially equivalent to the predicate.

Biocompatibility

Biocompatibility classification is based on the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO 10993-1, “Biological Evaluation of Medical Devices Part 1: Evaluation and Testing”

The TR BAND® Radial Compression Device is classified as Surface Device, Breached/Compromised Surface, Limited Contact (<24 hours). This is the same classification as the predicate TR Band (K070423).

The following tests are recommended by FDA and ISO 10993-1 to be performed per this device classification:

1. Cytotoxicity
2. Sensitization

3. Irritation/Intracutaneous reactivity
4. Acute systemic toxicity
5. Pyrogenicity
6. Material characterization

The full series of biocompatibility tests were conducted on the non-aged, sterile finished device except TR Band Inflator to demonstrate that all the test articles of the TR Band are biocompatible; furthermore, the limited testing was conducted on the accelerated-aged, sterile finished device except TR Band Inflator to demonstrate that aging does not affect the device's biocompatibility throughout its shelf life.

The TR Band Exclusive Inflator is an accessory device that is not patient contacting and was excluded from biocompatibility testing.

We conclude therefore that the biocompatibility of the finished TR Band is maintained throughout its shelf life.

Sterilization

The sterility of the device is assured using a sterilization method validated in accordance with ISO 11135:2014, Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices.

The TR BAND® Radial Compression Device is sterilized to provide a Sterility Assurance Level (SAL) of 10^{-6} .

Residual ethylene oxide (EO) and ethylene chlorohydrin (ECH) will meet requirements for limited exposure devices (contact up to 24 hours) prior to use based on EN ISO 10993-7:2008/Corr.1:2009, *Biological Evaluation of medical devices- Part 7: Ethylene Oxide Sterilization residuals*.

Residual EO will not exceed 4 mg per device and residual ECH will not exceed 9 mg per device after 24 hours of heat aeration.

Risk Analysis

A Product Risk Analysis was conducted in accordance with ISO 14971, and it was determined that any new risks were adequately captured and mitigated.

H. CLINICAL TESTS (807.92(b)(2))

This 510(k) does not include data from clinical tests.

I. CONCLUSION (807.92(b)(3))

In summary, the TR BAND® Radial Compression Device, subject of this 510(k), is substantially equivalent in its intended use, technology/principal of operation, materials, and performance to the predicate device(s):

K070423 – TR Band™, manufactured by Terumo Corporation, Japan