December 20, 2021

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

Re: K213531
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: November 4, 2021
Received: November 5, 2021

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. 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213531

Device Name
TR Band® Radial Compression Device

Indications for Use *(Describe)*
The TR Band® is a compression device indicated to apply compression in order to achieve hemostasis while allowing the user to maintain patency of the radial artery after a transradial procedure (patent hemostasis).

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

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

Section Contents

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 29, 2021

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:

- Predicate Device: K152525 - TR BAND® Radial Compression Device, manufactured by Terumo Medical Corporation, USA.
- Reference Device: K173563 - ARC Adjustable Radial Cuff Compression Device, manufactured by TZ Medical Inc.

D. REASON FOR 510(k) SUBMISSION

The subject 510(k) pertains to modifications to the Indications for Use and minor changes to the design.

E. 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.

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

The TR Band® is a compression device indicated to apply compression in order to achieve hemostasis while allowing the user to maintain patency of the radial artery after a transradial procedure (patent hemostasis). A comparison of the Intended Use between the subject, predicate, and reference device is provided below.

Device	**Subject Device:** TR BAND® Radial Compression Device	**Predicate Device:** TR BAND® Radial Compression Device (K152525)	**Reference Device:** ARC Adjustable Radial Cuff Compression Device (K173563)
Manufacturer	Terumo Medical Corporation	Terumo Medical Corporation	TZ Medical Inc

Intended Use / Indications for Use	The TR Band® is a compression device indicated to apply compression in order to achieve hemostasis while allowing the user to maintain patency of the radial artery after a transradial procedure (patent hemostasis).	The TR BAND® Radial Compression Device is a compression device to assist hemostasis of the radial artery after a transradial procedure.	When applied by a trained health care professional, the TZ Medical ARC™ device is indicated to assist in controlled compression hemostasis of the radial artery after a transradial procedure; the device is indicated to compress the radial artery access puncture site in order to achieve hemostasis and maintain patency of the radial artery (patent hemostasis).

Although the wording of the Indications for Use statements differ between the subject and predicate devices, the intended use and primary function of both the devices are the same. Both devices are intended to assist hemostasis of the radial artery after a transradial procedure. Furthermore, the ARC Adjustable Radial Cuff Compression Device manufactured by TZ Medical Inc (reference device: K173563) has the similar indications for use with regard to patent hemostasis.

G. 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 Medical Corporation.

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

Table 5.1: Summary of Substantial Equivalence

Device Characteristic	**Subject Device:** TR BAND® Radial Compression Device	**Predicate Device:** TR BAND® Radial Compression Device (K152525)
Manufacturer	Terumo Medical Corporation	Terumo Medical Corporation
Intended Use / Indications for Use	The TR Band® is a compression device indicated to apply compression in order to achieve hemostasis while allowing the user to maintain patency of the radial artery after a transradial procedure (patent hemostasis).	The TR BAND® Radial Compression Device is a compression device to assist hemostasis of the radial artery after a transradial procedure.
Operation Principle	Same	Operated manually or by a manual process; Pneumatic compression balloons are filled to apply pressure to the access site

Design / Construction	Same	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.
Materials	**TR Band - Band (Belt)** • Belt - Same • Compression balloon (large) - Same • Compression balloon (small) - Same • Green dot on Compression balloon (large) - Printing ink (green) • Tube - Same • Adjustable fastener - Same	**TR Band - Band (Belt)** • Belt - Polyvinyl chloride • Compression balloon (large) - Polyvinyl chloride • Compression balloon (small) - Polyvinyl chloride • Green dot on Compression balloon (small) - Printing ink (green) • Tube - Polyvinyl chloride • Adjustable fastener - Nylon
	Support plate Same	**Support plate** - Polycarbonate
	Valve Connector - Methylmethacrylate Acrylonitrile Butadiene Styrene (MABS) - Green Ink (Green air direction symbol)	**Pressure Confirmation Balloon** - Polyvinyl chloride - Printing Ink (Green air direction symbol)
	Air Injection Port with Valve Same	**Air Injection Port with Valve** • Valve o Valve overcoat - ABS resin - Colorant o Rubber valve - EPDM o Spring - Stainless steel
	TR Band - Inflator Same	**TR Band - Inflator** • 20mL syringe - Polypropylene (PP), etc. • Hub (Inflator tip/Syringe tip) - Polypropylene - Colorant • Label - Polyethylene - Colorant
	Individual Package (Unit Pouch) Same	**Individual Package (Unit Pouch)** • Printed Top Web - 1059B Tyvek coated with CR27 coating • Bottom Web - 6763 clear uncoated PETG

Package	Same	Lidded tray Shelf Box Shipping Carton
Specifications	Same	Length of band (belt): Large TR Band is 24 cm Large TR Band is 29cm
Sterilization	Same	Ethylene Oxide (validated in accordance with ANSI / AAMI / ISO 11135-1 to achieve SAL 10^{-6})
Shelf life	Same	30 months
Disposable Single Use	Same	Yes

The high-level overall design and construction of the subject TR BAND® Radial Compression Device are the same as those of the predicate device (K152525) with the exception of the minor design differences to the following components:

TR Band – Band:

- Compression Balloons
- Inflation Port
- Adjustable Fastener
- Belt
- Support Plate
- Green Marker (Green Dot)

TR Band – Inflator:

- Inflator Tip (also called Inflator Hub or Syringe Tip)

H. NON-CLINICAL TESTS (807.92(b)(1))

Performance

Performance testing was conducted to ensure the safety and effectiveness of the subject TR BAND® Radial Compression Device throughout the shelf life, verify conformity to the applicable external and internal standards, and demonstrate substantial equivalence to the predicate device. No issues of safety and effectiveness were raised with the testing performed. **Tables 5.2** below provide a list of the performance tests that were performed on the TR BAND® Radial Compression Device.

Table 5.2: Summary of Performance Testing

Standard Designation	Standard Name
ASTM F1980-16	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 F88/F88M-15	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM F2825-18	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	- Visual/Appearance - Dimensional - Functional performance o Tensile tests o Torque tests o Shear Strength tests o Pressure and Leak tests

The TR BAND® Radial Compression Device tested met the predetermined acceptance criteria. Based on the results of the performance testing, the subject TR BAND® is safe and effective for its intended use. There are no new issues of safety and effectiveness in the performance of the device.

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, and there were no new issues of safety or effectiveness.

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

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

J. 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):

- Predicate Device: K152525 - TR BAND® Radial Compression Device, manufactured by Terumo Medical Corporation, USA.
- Reference Device: K173563 - ARC Adjustable Radial Cuff Compression Device, manufactured by TZ Medical Inc.

There is no significant difference that raises any new issues of safety and effectiveness.