January 10, 2018

TZ Medical, Inc.
John Lubisich
President
17750 SW Upper Boones Ferry Rd #150
Portland, Oregon 97224

Re: K173563
Trade/Device Name: ARC Adjustable Radial Cuff Compression Device
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: November 10, 2017
Received: November 17, 2017

Dear John Lubisich:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Nicole G. Ibrahim -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173563

Device Name

ARC Adjustable Radial Cuff compression Device

Indications for Use *(Describe)*

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).

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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A.) Submitter Name and Address: TZ Medical, Inc.
17750 SW Upper Boones Ferry Rd #150
Portland, OR 97224
Phone: 503-639-0282
FAX: 503-639-0239

B.) Submitter's Establishment and Registration Number: TZ Medical Inc. 3027815

C.) Contact Person: John Lubisich
Management Representative
TEL: 503-639-0282
FAX: 503-639-0239

D.) Date of Summary:

E.) Trade name/Date of Summary:

F.) Trade name/Proprietary: ARC Adjustable Radial Cuff

G.) Common Name: Cardiovascular, Vascular Clamp, Compression Device

H.) Classification Name: Cardiovascular (Vascular Clamp) Surgical device

I.) Classification: CLASS II, per 21 CFR 870.4450

J.) Product Class/Panel: DXC, Cardiovascular

K.) Predicate Device:

Product	510K Number
Terumo Medical: TR Band Radial Compression Device	K152525

L.) Device Description:

The TZ Medial ARC Adjustable Radial Cuff "ARC" compression device is used at the end of a Transradial catheterization procedures to provide hemostasis of the radial artery at the access site. The ridged brace designed radial compression device consisting of a rigid polycarbonate "C" shaped brace, a flexible strap containing a PVC backing, hook and loop fasteners, and two buckles which attach to the ends of the brace, a collapsible bubble fixed to an adjustable slider with an air fill tube and universal luer lock, as well as back pad opposite of the bubble for patient comfort. Each device also includes a standard 20cc male luer locking syringe.

The Cuff is positioned around the patient's wrist and secured in place by fastening and tightening the Back Hook and Strap Assembly. As the introducer sheath is removed from the patient's wrist, pressure is applied to the access site by inflating the compression bubble of the ARC device. The bubble is inflated when air is injected through a luer lock air injection port which assures the desired air volume/pressure remains in the compression bubble. The volume/pressure in the bubble can be titrated by the physician to meet the hemodynamic needs of the patient by increasing or decreasing the volume in the ARC device bubble.

The ARC devices is intended for a single use only with a Functional life is less than 24 hours. This device is individually packaged and sterilized by ethylene oxide gas.

M.) Performance Testing:

a. Performance testing was conducted to verify conformity to applicable external and internal standards. All testing meant acceptance criteria of the below listed Standards and test procedures.

Standard Designation	Standard Name
ISO 10993-1	Biological Evaluation of Medical Devices Part 1 Evaluation and Testing
ISO 14971	Medical Devices- Applications of Risk Management to medical devices
ISO 15223-1	Medical device- Symbols to be used with medical device labels, labeling and information to be supplied- Part 1 general requirements
ISO 11135-1	Sterilization of Healthcare products- Ethylene Oxide Requirements for Development, Validation and Routine Control of Sterilization Process of Medical Devices
ISO 13485	Medical devices- Quality management systems- Requirements for regulatory purposes.
ISO 11607-1	Requirements for materials, sterile barrier systems and packaging systems
Internal Standards:	Included, but not limited to: Visual/Appearance Dimensional Functional Performance

N.) Non Clinical Data: Design Verification (DV) functional performance testing was completed to demonstrate that the ARC Adjustable Radial Cuff is substantially equivalent to the predicate. The testing included in-vitro engineering and bench testing on components and finished devices which were representative of commercial device and including, but not limited to: Visual/Appearance, Dimensional, Nonclinical and Functional Performance.

O.) ARC Indication for Use: 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).

P.) Terumo Medical Predicate Indication for Use: The TR BAND® Radial Compression Device is a compression device to assist hemostasis of the radial artery after a transradial procedure.

Q.) Comparison to Predicate Devices: The substantial equivalence of the TZ Medical ARC Adjustable Radial Cuff is based on an equivalence in intended use, method of operation and action, materials, and relative indications and contraindications, meeting internal and external standards to the predicate device, Terumo Medical TR Band Radial Compression Device K152525.

Item	Terumo TR Band™	TZ Medical ARC™	Comments
Manufacturer	Terumo Corporation	TZ Medical LLC	
Intended Use	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 care professional, the TZ Medical ARC device is designed to assist in controlled compression hemostasis of the radial artery after a transradial procedure, the device is designed to compress the radial artery access puncture site in order to achieve hemostasis and maintain patency of the radial artery (patent hemostasis).	Equivalent
Operational Principle	Operated manually, Pneumatic compression two balloons are filled to apply pressure to the access site	Operated manually, Pneumatic compression a double stacked balloon is filled to apply pressure to the access site.	Equivalent
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Equivalent
Packaging	Unit Pouch Shelf Box Shipping Carton	Unit Pouch Shelf Box Shipping Carton	Equivalent
Shelf Life	30 months	30 months	Equivalent
Single Use/Disposable	Yes	Yes	Equivalent

R.) Conclusion: The TZ Medical ARC Adjustable Radial Cuff device, subject of this 510(k), is substantially equivalent in its intended use/indication for use, technical/principals of operation, materials and performance to the Terumo Medical Corporation TR Band (K152525).