May 22, 2026

TZ Medical, Inc.
John Lubisich
President
20497 SW Teton Ave.
Tualatin, Oregon 97062

Re: K252772
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: April 23, 2026
Received: April 24, 2026

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Katherine N. Trivedi -S
Digitally signed by Katherine N. Trivedi -S
Date: 2026.05.22 12:47:59 -06'00'

Katherine Trivedi
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K252772

Device Name
TZ Medical ARC™ Adjustable Radial Cuff Compression Device

Indications for Use *(Describe)*
When applied by a trained health 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 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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A.) Submitter Name and Address:

TZ Medical, Inc.
20497 SW TETON AVE
TUALATIN, OR 97062
Phone: 503-639-0282
FAX: 503-639-0239

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

C.) Contact Person:

John Lubisich
PRRC
TEL: 503-639-0282
FAX: 503-639-0239

D.) Date of Summary: 04/10/2026

E.) Trade name/Proprietary: ARC Radial Compression Device

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

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

H.) Classification: CLASS II, 21 CFR 870.4450

I.) Product Class/Panel: DXC, Cardiovascular

J.) Predicate Device:

Product	510K Number
TZ MEDICAL ARC RADIAL COMPRESSION DEVICE	K173563

K.) Functional Performance Characteristics:

The ARC Radial Compression Device is a single-use, non-invasive device intended to provide controlled compression to the radial artery access site following transradial procedures.

The device consists of:

- Rigid polycarbonate brace
- Adjustable strap assembly
- Inflatable compression bubble
- Luer lock inflation system
- Patient comfort back pad

The device allows controlled pneumatic compression to achieve hemostasis while maintaining radial artery patency.

L. Intended Use

When applied by a trained health 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 indicated to compress the radial artery access puncture site in order to achieve hemostasis and maintain patency of the radial artery (patent hemostasis).

M. Technological Characteristics

The subject device is substantially equivalent to the predicate device (K173563) in:

- Intended use
- Design
- Materials
- Method of operation

Difference:
The subject device is sterilized using chlorine dioxide gas rather than ethylene oxide.

This change in sterilization method does not alter the device's intended use, design, or performance characteristics. The impact of this change has been evaluated through sterilization validation, biocompatibility testing, and toxicological risk assessment.

Biocompatibility testing was performed on the final chlorine dioxide sterilized device specifically to evaluate the impact of the sterilization method change.

N. Sterilization

The device is provided sterile and intended for single use.
Sterilization is performed using a validated chlorine dioxide sterilization process in accordance with ISO 14937.

- Sterility Assurance Level (SAL): 10^{-6}
- Validation includes:
  - Half-cycle and full-cycle validation
  - Biological indicators and process challenge devices (PCDs)
- Residuals evaluated using a toxicological risk assessment in accordance with ISO 10993-17

Residual testing confirmed that chlorine dioxide sterilization byproducts, including chlorite and chlorate, are present at levels below toxicological safety thresholds established through a risk assessment in accordance with ISO 10993-17.

O. Biocompatibility

Biocompatibility testing was conducted in accordance with ISO 10933. Testing was performed on the final sterilized device to evaluate potential effects of the chlorine dioxide sterilization process.

P. Performance Testing

Non-clinical performance testing was conducted to demonstrate safety and effectiveness.

Testing included:

- Functional performance testing
- Packaging validation (ISO 11607)
- Transportation testing (ASTM D4169)
- Environmental conditioning (ASTM D4332)

All testing met acceptance criteria.

Q. Substantial Equivalence

The ARC Radial Compression Device is substantially equivalent to the predicate device (K173563).

The only difference is the sterilization method.

This change has been evaluated through:

- Sterilization validation (ISO 14937)
- Biocompatibility testing (ISO 10993 series)
- Toxicological risk assessment of residuals

These evaluations demonstrate that the change in sterilization method does not raise new questions of safety or effectiveness.

The change in sterilization method does not introduce new materials or alter the patient-contacting components of the device.

R. Conclusion

The subject device is substantially equivalent to the predicate device.