August 13, 2024

Ningbo DIZEGENS Medical Science Co., Ltd.
Liqin Wang
U.S. Agent
Floor 3&4, Building A4, No. 777, Binhai 4th Road
Qianwan New Area.
Ningbo, Zhejiang Province, P.R. China. 315336

Re: K232577
Trade/Device Name: Radial Compression Device
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular clamp
Regulatory Class: Class II
Product Code: DXC

Dear Liqin Wang:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated January 18, 2024. Specifically, FDA is updating this SE Letter and the submitter information section of the 510k Summary to correct a typographical error in the company name from "DIZENGENS" to "DIZEGENS" as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Katherine Trivedi, OHT2: Office of Cardiovascular Devices, 240-402-6398 or Katherine.Trivedi@fda.hhs.gov.

Sincerely,

Carmen G. Johnson -S

for 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

January 18, 2024

Ningbo DIZENGENS Medical Science Co., Ltd.
Liqin Wang
Floor 3&4, Building A4, No. 777, Binhai 4th Road, Qianwan
New Area, Ningbo, Zhejiang Province, P.R. China. 315336

Re: K232577
Trade/Device Name: Radial Compression Device
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular clamp
Regulatory Class: Class II
Product Code: DXC
Dated: December 5, 2023
Received: December 19, 2023

Dear Liqin Wang:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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,

Rachel E. Neubrander -S

Rachel Neubrander, PhD
Division 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)*
K232577

Device Name
Radial Compression Device

Indications for Use *(Describe)*
The radial compression device is designed to apply compression in order to achieve temporary hemostasis of the radial artery after a percutaneous 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.

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

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510(k) Summary

K232577

A. Submitter Information

Submitter Name: Ningbo DIZEGENS Medical Science Co., Ltd.
Submitter Address: Floor 3&4, Building A4, No. 777, Binhai 4th Road, Qianwan New Area, Ningbo, Zhejiang Province, P.R. China. 315336
Phone: +86-574-82359758
Fax: +86-574-82359059
Contact Person: Zhang Wenwei, Vice General Manager
Email: edwardzhang@dizegens.com
Date Prepared: January 16, 2024

B. DEVICE

Trade Name: Radial Compression Device
Common Name: Radial compression device
Classification Name: Vascular Clamp
Classification Panel: Cardiovascular
Regulation: 21 CFR 870.4450
Classification: Class II
Product Code: DXC

C. Predicate Device

The legally marketed device(s) to which substantial equivalence is claimed is the Beijing Demax Medical Technology Co., Ltd. Radial Artery Compression Tourniquets (K222182).

D. Device Description

The Radial Compression Device (RC-001) is designed to promote hemostasis of the radial artery post percutaneous puncture. The radial compression device is fixed on the arm and the square pad of the device is pressed against the puncture site. The square cushion is adjusted to apply pressure and temporarily compress the puncture site of the radial artery to achieve rapid hemostasis. The product is primarily composed of a plate, turn cap, screw rod, hook and loop band, tapered cushion, and square cushion. The Radial Compression Device is available in one model, RC-001.

E. Indications for Use

The Radial Compression Device is designed to apply compression in order to achieve temporary hemostasis of the radial artery after a percutaneous transradial procedure. The intended use is the same as the predicate device and does not raise new questions of safety or effectiveness.

F. Comparison of Technological Characteristics

The Radial Compression Device and predicate Radial Artery Compression Tourniquets (K222182) affix a hook and loop band onto the patient's wrist following a percutaneous radial artery puncture. Both devices operate by turning a screw, which applies additional force, to the puncture site to achieve temporary hemostasis of the radial artery. The Radial Compression Device incorporates substantially equivalent indications for use, design, operating principles, and sterilization process as those shared by the predicate Radial Artery Compression Tourniquets (K222182).

G. Summary of Non-Clinical Performance Testing

The following performance testing was provided to support substantial equivalence between the Radial Compression Device and the predicate device:

- Visual inspections
- Dimensional inspections
- Bond strength testing
- Turn Cap and Screw Function
- Distribution and Packaging Tests
- Device and Packaging Aging Evaluation
- Pressure applied at puncture site
    - Testing was conducted to demonstrate that the Radial Compression Device applies adequate pressure to compress the radial puncture site.

Biocompatibility evaluation per ISO 10993:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Pyrogenicity
- Hemolysis

Sterilization

- The Radial Compression Device is intended for single use only and is provided sterile via ethylene oxide (EO) gas to achieve a Sterility Assurance Level (SAL) of 10^{-6} per ISO 11135. An EO/ECH residuals assessment found the residuals to be within acceptable limits per 10993-7.

All testing met the requirements and passed.

H. Conclusion

The Radial Compression Device is substantially equivalent to the predicate device.