September 19, 2022

Zien Medical Technologies, Inc.
Tim Nieman
CEO
2757 South 300 West Suite F
Salt Lake City, Utah 84115

Re: K214060
Trade/Device Name: LANDMARK REBOA Catheter
Regulation Number: 21 CFR 870.4450, 21 CFR 870.1250
Regulation Name: Vascular clamp, percutaneous catheter
Regulatory Class: Class II
Product Code: MJN, DQY
Dated: August 8, 2022
Received: August 10, 2022

Dear Tim Nieman:

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,

for Carmen Gacchina Johnson, PhD
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)*
K214060

Device Name
LANDMARK REBOA Catheter

Indications for Use *(Describe)*
The LANDMARK REBOA Catheter is intended for temporary occlusion of large vessels including patients requiring emergency control of hemorrhage.

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
(21 CFR 807.92)

GENERAL INFORMATION

Submitted by:

Owner's Name: ZIEN Medical Technologies, Inc.
Address: 2757 South 300 West Suite F
Salt Lake City, UT 84115

Contact Person:

Name: Tim Nieman
Title: Chief Executive Officer
Tel: +1 (801) 891-8610
Email: tim.nieman@zienmedical.com

FDA Registration Number: 3009756153

Date Prepared: September 15, 2022

Trade Name: LANDMARK REBOA Catheter

Regulation Name: Vascular Clamp and Percutaneous Catheter

Classification Name:

- 21 CFR §870.4450, Product Code: MJN Catheter, Intravascular Occluding, Temporary
- 21 CFR §870.1250, Product Code: DQY Percutaneous Catheter

Classification Panel: Cardiovascular

Regulatory Class Class II

Predicate Device: ER-REBOA™ Catheter (K172790), Manufactured by Prytime Medical Devices, Inc. (Boerne TX)

DEVICE DESCRIPTION:

The LANDMARK REBOA Catheter is a 67cm, 59cm working length, 6.5 Fr (2.2mm), single lumen balloon catheter for temporary intravascular vessel occlusion in patients requiring emergency control of hemorrhage. Radio-opaque markers are provided on the catheter shaft at the proximal and distal ends of the balloon for radiological location of the balloon. The device is additionally provided with depth markings referenced from the center of the balloon to provide positioning information similar to the predicate device prior to confirmation of placement through radiological means. The device is intended to be deployed through a 7F introducer sheath placed into the femoral artery through normal vascular access procedures.

The LANDMARK REBOA Catheter consists of five elements:

- Occluder Balloon Inflation Lumen with female luer (DEHP free PVC)
- Catheter Handle (PA 12)
- Catheter Shaft (polyimide and stainless steel) with Marker Bands (stainless steel)
- Occluder Balloon (polyurethane)
- Guide J-tip (stainless steel, nitinol, acrylic)

INDICATIONS FOR USE:

The LANDMARK REBOA Catheter is intended for temporary occlusion of large vessels including patients requiring emergency control of hemorrhage.

LABELING AND TECHNOLOGICAL CHARACTERISTICS COMPARISON:

As shown in Table 1, the proposed LANDMARK REBOA Catheter has **equivalent** intended use and **similar** technology characteristics to the currently marketed ER-REBOA (K172790). Technological and Intended use differences include the lack of a secondary lumen in the subject device to monitor the patient's blood pressure, which can be monitored through more common means.

Table 1: Comparison Table

	SUBJECT DEVICE	PREDICATE DEVICE
1. LABELING		
Intended use	The LANDMARK REBOA Catheter is intended for temporary occlusion of large vessels including patients requiring emergency control of hemorrhage	The ER-REBOA Catheter is intended for temporary occlusion of large vessels and blood pressure monitoring including patients requiring emergency control of hemorrhage
Rx or OTC	Rx	Same
Target population	Adult patients in need of large vessel occlusion	Same
Contraindications	Known allergic reactions to contrast media	Same

	Table 1: Comparison Table	
	SUBJECT DEVICE	**PREDICATE DEVICE**
	Do not have a femoral access site that can accommodate a 7Fr (minimum) introducer sheath	Similar
	Have an aortic diameter larger than 30mm	
	Are minors (younger than 18 years old)	Same
2. TECHNOLOGY		
Use Environment (Where used)	Emergency settings, Pre-hospital, In hospital, Acute Care, Military	Same
Insertion site	Femoral Artery	Same
Insertion depth assessment	Radiographic location using radio-opaque markers and/or radio-opaque inflation media	Similar; predicate permits fluoroscopy as optional
Mode of action	The user inserts the catheter through femoral access using depth marks and/or radiological confirmation of location wherein the balloon can be inflated using volume as indicator to provide occlusion of the vessel.	Same
3. CHARACTERISTICS		
Sterile single use components and accessories	A pre-loaded peel-away sheath is provided to aid introduction of the catheter tip into the introducer sheath.	A peel-away sheath is preloaded on the catheter shaft to ease insertion of the catheters P-tip into an introducer sheath hemostasis valve
Lengths offered	59 cm working length	64 cm working length (Similar)
Depth indicator markings on cannula	White indicator lines are located at 1 cm increments from the center of the balloon for assessing insertion depth.	Same
Maximum Balloon Diameter	30mm	32mm (Similar)
Introducer Sheath Compatibility	7Fr	Same
Shelf life	12 months (1 year)	3 years
Sterility	Ethylene Oxide (EO), SAL 10^{-6}	Same
Biocompatibility Per ISO 10993	• External Communicating device • Contacting Circulating Blood • Limited Duration (≤ 24h)	Same

NON-CLINICAL TESTING

Performance (Bench) and Comparative Testing: Performance bench testing was conducted to ensure that the LANDMARK REBOA Catheter met the applicable design and performance requirements throughout its shelf life, verify conformity to applicable standards, and demonstrate substantial equivalence to the predicate system. The following performance testing listed below was performed or fulfilled with the LANDMARK REBOA Catheter:

- Balloon Burst Testing
- Balloon Inflation/Deflation Testing
- Balloon Diameter to Inflation Volume Testing
- Occlusion Time Testing
- Torque Testing
- Kink Diameter Testing
- Fatigue Testing
- Freedom From Leakage Testing
- Tensile Strength Testing
- Dimensional Testing
- Maximum Inflation Volume Testing
- Shelf-Life Testing

Simulated use: Simulated use results provided by ZIEN Medical Technologies, Inc. support the conclusion that the proposed device is clinically safe for prescription use. Furthermore, ZIEN Medical Technologies, Inc. conducted a risk analysis on the proposed system in accordance with ISO 14971:2019. All identified risks have been addressed through device design, verification/validation or through documentation (labeling and Instructions for Use) provided to the user.

Biocompatibility: The patient-contacting (direct/indirect fluid path) components of the LANDMARK REBOA Catheter, fulfil the requirements as set forth in:

- *ISO 10993: Biological evaluation of medical devices – Part 1: Guidance on selection of tests for and External Communicating Device, Circulating Blood, A-Limited (<24 hr) duration.*

Sterilization: The LANDMARK REBOA Catheter is sterilized via ethylene oxide (EO) sterilization. The sterility to a Sterility Assurance Level (SAL) of 10^{-6} is assured using a validated EO sterilization method.

Packaging: The sterilization validation, stability (accelerated aging followed by seal integrity and seal strength testing) testing and package (sealing process) validation results demonstrate that the proposed terminally sterilized packaging system allows sterilization, provides physical protection, maintains sterility up to the point of use and allows aseptic presentation of the LANDMARK REBOA Catheter.

In Vivo Testing: Performance evaluation of the LANDMARK REBOA Catheter was performed in the aorta of an acute Porcine model to demonstrate the catheter meets applicable design and performance requirements and is substantially equivalent to the predicate device.

CONCLUSION OF COMPARISON

Based on the performance testing conducted and provided in this submission, it was concluded that the LANDMARK REBOA Catheter is substantially equivalent to the ER-REBOA (K172790).