April 18, 2025

TamaBio
% Michael Nilo
Principal Consultant, Nilo Medical Consutling, LLC
Nilo Medical Consulting Group, LLC
3491 Denny Street
#313
Pittsburgh, Pennsylvania 15201

Re: K240775
Trade/Device Name: PeriBeam® Pericardial Membrane
Regulation Number: 21 CFR 870.3470
Regulation Name: Intracardiac Patch Or Pledget Made Of Polypropylene, Polyethylene Terephthalate, Or Polytetrafluoroethylene
Regulatory Class: Class II
Product Code: DXZ
Dated: March 10, 2025
Received: March 11, 2025

Dear Michael Nilo:

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.

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,

ALEXANDRA K. MANARAS -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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
*See PRA Statement below.*

Submission Number *(if known)*

K240775

Device Name

PeriBeam® Pericardial Membrane

Indications for Use *(Describe)*

The PeriBeam® Pericardial Membrane is indicated for the reconstruction or repair of the pericardium.

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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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# K240775 - 510(k) Summary

| | |
|---|---|
| **Date Prepared:** | April 17, 2025 |
| **Applicant Name** | TamaBio |
| **Applicant Contact** | Mr. Tetsuya Nagao |
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| **Correspondent Name** | Nilo Medical Consulting Group, LLC |
| **Correspondent Contact** | Michael Nilo, President |
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| **Correspondent Telephone** | +1 717.421.4396 |
| **Correspondent Email** | michael.nilo@nilomed.com |
| **Device Trade Name** | PeriBeam® Pericardial Membrane |
| **Common Name** | Intracardiac patch or pledget made of polypropylene, polyethylene, terephthalate, or polytetrafluoroethylene |
| **Classification Name** | Patch, Pledget and Intracardiac, PETP, PTFE, Polypropylene |
| **Regulation #** | 870.3470 |
| **Product Code(s)** | DXZ |
| **Predicate Name** | PRECLUDE® Preicardial Membrane |
| **Predicate Number** | K012098 |
| **Predicate Product Code** | DXZ |

## Device Description

PeriBeam® is an ion-irradiated, expanded polytetrafluoroethylene (ePTFE) membrane used for reconstruction or repair of the pericardium. This device is intended for use as a temporary or permanent prosthesis for repair of pericardium

## Indications for Use

The PeriBeam® Pericardial Membrane is indicated for the reconstruction or repair of the pericardium.

The indications for use are the same as the predicate device

## Technological Comparison

Concerning the technological characteristics, while the PeriBeam® and PRECLUDE® are made of the same ePTFE and have nearly identical technological characteristics, the difference is the use of ion-irradiation on one surface of the PeriBeam® Pericardial Membrane. The ion beam etching on the patch is designed to create an adhesive surface for the pericardium.

The indications for use, materials, supplied dimensions, thickness, sterilization, packaging, biological safety and performance characteristics are all similar to the predicate device.

## Performance Testing

The PeriBeam® Pericadial Membrane has undergone the following nonclinical, performance testing: Tensile Strength (ISO 2859-1), Suture Strength (ISO 2859-1), Accelerated Fatigue, Fibrin Glue (Leak and Peel tests) and Burst Strength (JIS L1096 8.18, ISO 13938-1).

1. Accelerated Fatigue Testing was conducted to evaluate cardiac function (heart beating) on the tensile strength of the ePTFE.
2. Tensile Strength testing, in accordance with ISO2859-1, was conducted to evaluate the tensile strength of ePTFE sheet after ion irradiation, as well as for design validation.
3. Suture Strength testing, in accordance with ISO 2859-1, was conducted to verify mechanical safety due to the device being used to cover pericardial defects and fixed in place by surgical sutures.
4. Fibrin glue tests were conducted to evaluate PeriBeam®'s compatibility with Fibrin glues. This included Leak and Peel testing.
5. Burst Strength Testing – Burst strength testing was conducted to determine the pressure under which the PeriBeam® device would fail. The base standard for this test is JIS L1096 8.18, which is the equivalent standard to ISO 13938-1.

## Animal Testing

An animal study was conducted in support of the PeriBeam® Pericardial Membrane, providing additional safety information and demonstration of the device's ability to meet its intended use. Pericardium implantation and autopsy was conducted using ten (10) pigs divided into three (3) groups for eight (8) weeks. The following endpoints were evaluated:

- Treated site observations: health condition, feeding, respiration, feces etc. and macroscopic observations of the treated site
- Weight measurement
- Ultrasonography results: pericardial effusion, adhesion, and heartbeat
- Autopsy measurements: adhesions with the thorax organs, adhesions with the heart, pericardial, pleural effusion, infection, and discharge
- Histopathology: inflammatory (cellular infiltration of neutrophils, lymphocyte, macrophage and foreign body giant cell), amount of fibroblast, fibrosis, existence of bacteria

## Biological and Toxicological Safety Testing

The following endpoints were evaluated in accordance with ISO 10993.

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Material Mediated Pyrogenicty
- Subacute Toxicity
- Implantation
- Genotoxicity
- Chronic Toxicity
- Carcinogenicity
- Hemolysis
- Chemical Characterization

## Sterilization and Packaging

The PeriBeam® is steam sterilized with an SAL of $10^{-6}$. This was validated using JIST 0186-1:2010(ISO 17665-1:2006), ISO 11135, ISO 11737-1,

The shelf-life packaging validation was completed to support shelf, in accordance with the following standards: ISO 11607-1:2019: Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems, and packaging systems, ASTM F1980 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices, ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices, ASTM F2096, Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test), and ASTM F88, Standard Test Method for Seal Strength of Flexible Barrier Materials.

## Conclusion

The PeriBeam® Pericardial Membrane is substantially equivalent to the predicate device.