July 24, 2024

PENTAX of America, Inc.
Gurvinder Singh Nanda
Senior Director, Regulatory and Quality
3 Paragon Drive
Montvale, New Jersey 07645

Re: K240457
Trade/Device Name: C2 CryoBalloon Ablation System (C2 CryoBalloon Ablation System)
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: June 21, 2024
Received: June 21, 2024

Dear Gurvinder Singh Nanda:

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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2024.07.24 08:36:02 -04'00'

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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.

510(k) Number *(if known)*
K240457

Device Name
C2 CryoBalloon Ablation System

Indications for Use *(Describe)*
The C2 CryoBalloon™ Ablation System is intended to be used as a cryosurgical tool in the field of general surgery, specifically for endoscopic applications, to include ablation of Barrett's Esophagus with dysplasia and treatment and management of Gastric Antral Vascular Ectasia (GAVE).

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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PENTAX Medical
C2 CryoBalloon™ Ablation System
510(k) Premarket Notification(K240457)

510(k) Summary

I. SUBMITTER

PENTAX of America
3 Paragon Drive
Montvale, NJ 07645
Phone: 650-722-4189

Contact Name: Gurvinder Singh Nanda, PhD.
Date Prepared: June 19, 2024

II. DEVICE

Name of Device: C2 CryoBalloon™ Ablation System
Common or Usual Name: Cryosurgical Unit and Accessories
Classification Name: Cryosurgical Unit and Accessories
Regulatory Class: 21 CFR §878.4350
Product Code: GEH

III. PREDICATE DEVICE

C2 CryoBalloon™ Ablation System, K212814

IV. REFERENCE DEVICE

BARRX Medical HALO^{90} System, K093008

V. DEVICE DESCRIPTION

The subject device is a cryosurgical unit with a nitrous oxide cooled balloon that is compatible with commercially available endoscopes with a minimum working channel inner diameter of 3.7 mm and maximum length of 105 cm. The subject device is a cryosurgical system comprised of four components including a Catheter (sterile, single use), Controller (non-sterile, reusable), Foot Pedal (non-sterile, reusable), and Cartridge (non-sterile, single use). The system also includes NitroClip as an accessory that is intended to reduce the nitrous oxide exposure in the room.

The subject device is used to ablate unwanted tissue by application of extreme cold. The balloon at the distal end of the Catheter comes in contact with tissue and is inflated with nitrous oxide. Tissue is visualized through the pre-inflated balloon, and the treatment site is selected by adjusting the endoscope and Controller. The nitrous oxide spray cools the balloon to ablate the unwanted tissue, and the nitrous oxide exhausts through the Controller.

VI. INDICATIONS FOR USE

The C2 CryoBalloon™ Ablation System is intended to be used as a cryosurgical tool in the field of general surgery, specifically for endoscopic applications, to include ablation of Barrett's Esophagus with dysplasia and treatment and management of Gastric Antral Vascular Ectasia (GAVE).

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Cryoablation is the fundamental technological principle for both the subject C2 CryoBalloon Ablation System and the predicate C2 CryoBalloon Ablation System (K212824). There have been no significant changes to the technological characteristics of the C2 CryoBalloon Ablation System since clearance of the predicate device. The subject and the legally marketed predicate device C2 CryoBalloon Ablation System have the same design, materials, energy source, and principles of operation.

The subject and the predicate devices are based on the following same technological elements:

• Inserted through an endoscope to access the treatment site

• Application of cryogen to ablate (freeze) the unwanted tissue

• Use of a compliant balloon to position the treatment diffuser and to contain and exhaust the cryogen

• User-controlled (trigger/foot pedal) to release cryogen

• Software activated Controller

The only difference is the indication of use of the subject device now includes treatment and management of Gastric Antral Vascular Ectasia (GAVE).

The inclusion in the labeling of a lower dose to treat patients with short segment Barrett's Esophagus (BE) using the subject C2 CryoBalloon 180◦ catheter is within the device's current intended use and indications for use. The change of the catheter's RFID value of Maximum Treatment Speed from 1.0mm/s to1.2mm/s for the lower dose falls under existing design verification and validation. The addition of this lower treatment rate is also supported by bench and clinical data demonstrating its safety and effectiveness.

Two caution statements have been removed from the Instructions for Use. These modifications are supported by bench and / or clinical data regarding the safety and effectiveness of its use, which do not raise different questions of safety and effectiveness.

VIII. PREFORMANCE DATA

A. Bench Testing

Bench testing was performed to verify the results of the temperature profiling data of the 180 Standard catheter at 1.0 mm/s and 1.2 mm/s speeds. The tests passed all acceptance criteria. Testing results verified

the spray radius and spray uniformity of the Standard 180 Catheter, confirming that the 180 Catheter can be used at speeds of 1.0 and 1.2mm/s.

Test method validation was performed for the C2 CryoBalloon Catheters that use the 180-degree diffuser. Temperature distribution tests were performed to verify temperature spray profiles for catheters, where the profile determines what percentage of the spray pattern reaches optimal temperatures for treatment. The results of the testing demonstrated that the temperature distribution can be produced consistently and accurately.

No animal data was used to support this 510(k) premarket notification.

B. Clinical Testing

1. Gastric Antral Vascular Ectasia (GAVE)

A multi-center retrospective study evaluated the C2 CryoBalloon ablation system focal for the treatment and management of GAVE. 28 subjects were included based on endoscopic report findings and history of clinical evidence of GAVE. All patients in the study had been previously treated to manage their GAVE disease with argon plasma coagulation (APC), radiofrequency ablation (RFA), liquid nitrogen cryotherapy (LNC) or were treatment naïve. The primary outcome was the mean number of packed red blood cells (PRBC) transfused before treatment versus after CryoBalloon ablation (CBA). Outcomes were compared to a published study of 33 GAVE patients that were treated with APC or RFA from three tertiary referral centers in the United States.

With the CryoBalloon ablation system treatment, technical success was 100% with no device malfunctions and no serious adverse events. Efficacy at 6 months was 71% for transfusion independence. Endoscopic success at 6 months was 88% GAVE eradication with 2.4 mean CryoBalloon ablation treatments.

Literature review shows clinical success for CryoBalloon ablation treatment (62-83%) is comparable to other modalities (50-100%). Blood hemoglobin increased 4.6 g/dl with CryoBalloon ablation treatment versus 2.55 g/dl with APC/RFA. Monthly packed red blood cell transfusions decreased by 0.77 units with CryoBalloon ablation treatment versus 1.45 units with APC/RFA.

Overall, the study shows CryoBalloon ablation treatment is effective for long-term GAVE treatment, with 6-month outcomes similar or better than other modalities and supported by literature review.

2. 180° Catheter Treatment dose

Two studies evaluated the safety and efficacy of the 180° CryoBalloon ablation catheter for treatment of Barrett's esophagus (BE) related. The first study enrolled 25 patients at a 1.0mm/s dose in a dose-finding phase to establish the effective dose that resulted in BE regression at 8-10 weeks of ≥60 %. The study's results demonstrated a median BE regression as evaluated of 90 % (95 % CI 70 %–90%) after a single 1.0mm/s treatment. Technical success was 96% per protocol. One patient (1/23; 4 %), developed a stricture that was resolved with two dilations. No severe bleeding, perforation, or other SAEs occurred. Five patients had adverse events. Three patients had moderate strictures not requiring dilation, one patient had dark

colored stools (no melena), which resolved spontaneously, and one patient experienced heavy chest pain on the day of treatment and additional analgesics were prescribed.

The second study was a multicenter study treating 25 patients with short segment BE using a lower 180° CryoBalloon Ablation catheter dose of 1.2mm/s. Average BE surface regression was 95% at a 3-month follow-up visit. One serious adverse event (post-procedure bleeding from a patient with double-dosed anti-coagulation therapy due to a pre-existing cardiac condition.) occurred which resolved. No strictures requiring dilation occurred. Two mild adverse events occurred post procedure in which no treatments were required.

In summary, both studies demonstrate the 180° CryoBalloon ablation system catheter is safe and effective for BE treatment using doses of 1.0mm/s and 1.2mm/s. Excellent technical success and BE regression were achieved with minimal adverse events. The data supports the lower dose labeling for short segment BE treatment.

IX. CONCLUSIONS

C2 CryoBalloon Ablation System meets all substantial equivalence criteria for use as a cryosurgical tool in the field of general surgery, specifically for endoscopic applications, to include ablation of Barrett's Esophagus with dysplasia and treatment and management of Gastric Antral Vascular Ectasia(GAVE) based on comparable use, technology, data, and minor differences not affecting safety/effectiveness.