November 24, 2020

PENTAX of America, Inc.
Gurvinder Nanda
Sr. Director, Regulatory Affairs
303 Convention Way, Suite 1
Redwood, CA, California 94063

Re: K203024
Trade/Device Name: C2 CryoBalloon Catheter (Pear), C2 CryoBalloon Catheter (Standard), C2 CryoBalloon Controller, C2 CryoBalloon Foot Pedal, C2 CryoBalloon Cartridge
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: September 30, 2020
Received: October 2, 2020

Dear Gurvinder 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 (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 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203024

Device Name
C2 CryoBalloon™ Ablation System

Indications for Use *(Describe)*
The C2 CryoBalloon™ Ablation System is intended 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.

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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510(k) Summary (K203024)

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

I. SUBMITTER

PENTAX Medical
A Division of PENTAX of AMERICA, Inc.
303 Convention Way, Suite 1
Redwood City, CA 94063

Phone/Fax: 650-316-8601

Contact Person: Gurvinder Singh Nanda, Ph.D.
Sr. Director, Regulatory Affairs

Date Prepared: September 30, 2020

II. DEVICE

Name of Device:	C2 CryoBalloon Ablation System
Common Name:	Cryosurgical Unit, Cryogenic Surgical Device
Classification Name:	Cryosurgical Unit, Cryogenic Surgical Device 21 CFR§878.4350(a)(2)
Regulatory Class:	Class II
Product Code:	GEH

III. PREDICATE DEVICE

C2 CryoBalloon Ablation System, PENTAX Medical (K190194)

IV. 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 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 is 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. A detailed comparison of the subject devices to the predicate devices is presented in detail in **Section 11** and **Section 12**.

V. INDICATIONS FOR USE

The C2 CryoBalloon Ablation System is intended 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.

VI. 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. Both devices are of the same exact design. There are no changes being made to the design or materials. Both the subject device and predicate device are based on the same endoscopic instrumentation 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.

The subject C2 CryoBalloon™ Ablation System has the same technological characteristics to the legally marketed predicate device (K190194). The subject devices and predicate/reference 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 modifications that are being made are to the C2 CryoBalloon Controller and Foot Pedal Reprocessing Instructions (LBL-1024) to simplify the reprocessing of the Controller component. There are no changes to the reprocessing (cleaning) of the Foot Pedal component. The subject device and predicate device are both intended to be cleaned and disinfected by the user between patient use.

VII. PERFORMANCE DATA

Performance data are provided in support of the substantial equivalence determination. Testing was performed on the subject C2 CryoBalloon Ablation System to evaluate cleaning validation, disinfection validation, and usability. All testing results met the acceptance criteria identified in the study protocol.

VIII. CONCLUSION

The subject C2 CryoBalloon Ablation System has the same clinical attributes, technological characteristics, intended use, and expected performance as the legally marketed predicate device, C2 CryoBalloon Ablation System (K190194). The performance testing results demonstrate that the subject C2 CryoBalloon Ablation System with modified Controller reprocessing instructions should perform as intended in the specified use conditions and should perform comparably to the legally marketed predicate device that is currently marketed for the same intended use.