May 31, 2019

PENTAX Medical, A Division of PENTAX of America, Inc.
Gurvinder Nanda
Senior Director of Regulatory Affairs
303 Convention Way, Suite 1
Redwood City, California 94063

Re: K190194
Trade/Device Name: C2 CryoBalloon Ablation System
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit and Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: May 2, 2019
Received: May 3, 2019

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

Jennifer R. Stevenson
Acting Division 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)*
K190194

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 (K190194)

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

I. SUBMITTER

PENTAX Medical
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Redwood City, CA 94063

Phone: (650) 316-8601
Fax: (650) 316-8601

Contact Person: Gurvinder Singh Nanda
Senior Director of Regulatory Affairs
Date Prepared: May 30, 2019

II. DEVICE

Name of Device: C2 CryoBalloon™ Ablation System (subject and predicate device)
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

Predicate: C2 CryoBalloon™ Ablation System, C2 Therapeutics Inc., (now PENTAX Medical) K163684

IV. DEVICE DESCRIPTION

The subject and marketed predicate 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 and marketed predicate 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 Catheter The nitrous oxide spray cools the balloon to ablate the unwanted tissue, and the nitrous oxide exhausts through the Controller.

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 the subject device and predicate device are based on the same endoscopic instrumentation for removing unwanted tissue using extreme cold.

The subject C2 CryoBalloon™ Ablation System has similar technological characteristics to the legally marketed predicate K163684. The subject devices and predicate 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 software changes that are being implemented in the subject device include:

Over-pressure monitoring post test puff,
Balloon pressure transducer check during system start up, and
Detection of a severely kinked Catheter.

The subject C2 CryoBalloon™ Ablation System has the same reuse characteristics as the legally marketed reference predicate K163684. The subject device and reference predicate are based on the same reuse elements of using a disinfectant wipe-down to clean and disinfect between uses.

VII. PERFORMANCE DATA

Performance data were provided in support of the substantial equivalence determination. Design verification and validation testing was performed on the subject PENTAX Medical C2 CryoBalloon™ Ablation System to evaluate physical, reliability, and safety specifications. The acceptance criteria have been satisfied for all tests.

Sterilization

The subject PENTAX Medical C2 CryoBalloon™ Ablation System and predicate devices are both sterilized utilizing an Ethylene Oxide sterilization cycle validated in accordance with ISO 11135 - Medical Devices - Validation and Routine Control of Ethylene Oxide Sterilization

Biocompatibility

The biocompatibility evaluation of the patient contacting materials of the PENTAX Medical C2 CryoBalloon™ Ablation System was conducted in accordance with "Guidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'" with passing results. Biocompatibility testing was not required for this change as there were no changes in patient contacting materials.

EMC and Electrical Safety

The acceptable level of electromagnetic compatibility (EMC) and electrical safety (ES) for the PENTAX Medical C2 CryoBalloon™ Ablation System were confirmed by the testing to the following standards: IEC 60601-1-2:2014 4th Edition and ES60601-1:2005/(R)2012 And A1:2012.

CONCLUSION

The subject C2 CryoBalloon™ Ablation System has the same clinical attributes, technological characteristics, and expected performance as the legally marketed predicate, C2 CryoBalloon™ Ablation System (K163684). The performance data results demonstrate that the subject C2 CryoBalloon™ Ablation System is as safe and effective as the legally marketed predicate that is currently marketed for the same intended use.