November 22, 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: K193036
Trade/Device Name: C2 CryoBalloon EndoGrip
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: OCX
Dated: October 30, 2019
Received: October 31, 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,

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)*
K193036

Device Name
C2 CryoBalloon™ EndoGrip

Indications for Use *(Describe)*
The C2 CryoBalloon™ EndoGrip is intended to provide access for endoscopic device passage and exchange throughout the endoscopic procedure.

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

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

Date Prepared: October 30, 2019

II. DEVICE

Name of Device: C2 CryoBalloon™ EndoGrip
Common Name: EndoGrip
Classification Name: Endoscopic and Accessories
Classification Code: 21 CFR §876.1500
Regulatory Class: Class II
Product Code: OCX

III. PREDICATE DEVICE

BOA Endoscopic Valve (K152140)

This predicate device has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The C2 CryoBalloon™ EndoGrip is an accessory product that is used in conjunction with therapeutic endoscopes and therapeutic catheters (the C2 CryoBalloon™ Catheter of the C2 CryoBalloon™ Ablation System). The C2 CryoBalloon™ EndoGrip consists of a Clip Base, Rubber Grip, and Compression Spring. This is supplied non-sterile. The EndoGrip is used to anchor catheters in place relative to the scope. In a clinical application, once the endoscope is delivered into the gastric anatomy and positioned at its

desired location the physician may insert the catheter through the endoscope. When the catheter is located properly in its axial position, the EndoGrip is positioned against the biopsy valve by depressing the clip mechanism and sitting the catheter on the rubber grips. The revised design allows for placing the EndoGrip after the CryoBalloon catheter is in place in the scope and for repositioning without having to completely withdraw and reinsert the catheter. The C2 CryoBalloon™ EndoGrip is designed for one-time, continuous application use (single patient) in conjunction with a therapeutic endoscope (3.7mm accessory channel ID) or a C2 Sidecar (FG -1011), which serves as an external channel for therapeutic devices when a therapeutic endoscope is unavailable for use.

V. INDICATIONS FOR USE

The C2 CryoBalloon™ EndoGrip is intended to provide access for endoscopic device passage and exchange throughout the endoscopic procedure.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject C2 CryoBalloon™ EndoGrip has similar technological characteristics to the legally marketed predicate C2 BOA Endoscopic Valve (K152140). The subject and predicate devices are based on the following same technological elements:

- Attached against the proximal biopsy channel port of an endoscopic device to provide endoscopic device passage and exchange
- Used in hospitals, sub-acute care institutions, surgery centers, or doctor's office where endoscopic procedures may be performed
- Used in single patient (disposable) undergoing endoscopic procedures

The following technological differences exist between the modified device and the predicate device:

The modified device is secured through the use of a spring-clip mechanism, and the predicate device is secured through the use of a twist-Tuohy tightening mechanism.

VII. PERFORMANCE DATA

The performance testing for the C2 CryoBalloon™ EndoGrip included:

1. Physical characteristic evaluations for dimensional verification
2. Simulated use, performance, and reliability testing were performed to verify the device can be attached to and detached from endoscope, withstand 10

endoscopic delivery cycles, compatible with endoscopic devices, resist dislodgement forces, and resist kinking.

3. Usability testing for validation of user needs

All the tests passed and met the predetermined acceptance criteria.

VIII. CONCLUSION

The subject C2 CryoBalloon™ EndoGrip has the same clinical attributes, technological characteristics and expected performance as the legally marketed predicate, C2 BOA Endoscopic valve (K152140). The performance data demonstrate that the subject C2 CryoBalloon™ EndoGrip performs as intended in the specified use conditions and performs comparably to the legally marketed predicate device that is currently marketed for the same intended use.