DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 19, 2016

C2 Therapeutics, Inc.
Ms. Theresa Brandner-Allen
VP of Regulatory Affairs and Quality Assurance
303 Convention Way, Suite 1
Redwood City, California 94063

Re: K160994
Trade/Device Name: C2 Cryoballoon Focal Pear Catheter
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit and Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: May 10, 2016
Received: May 11, 2016

Dear Ms. Brandner-Allen:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160994

Device Name

C2 CryoBalloon™ Focal Ablation System

Indications for Use *(Describe)*

The C2 CryoBalloon™ Focal Ablation System is intended to be used as a cryosurgical tool for the destruction of unwanted tissue in the field of general surgery, specifically for endoscopic applications.

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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5. 510(k) Summary

K160994

Special 510(k)

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

I. SUBMITTER

C2 Therapeutics, Inc.
303 Convention Way, Suite 1
Redwood City, CA 94063

Phone: 650-521-5921
Fax: 650-556-1145

Contact Person: Theresa Brandner-Allen
VP of Regulatory Affairs and Quality Assurance
Date Prepared: May 9, 2016

II. DEVICE

Name of Device: C2 CryoBalloon™ Focal Pear Catheter
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

CryoBalloon Focal Ablation System, K131523

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

IV. DEVICE DESCRIPTION

The subject device is the Catheter used as part of a cryosurgical unit with a nitrous oxide cooled balloon that is compatible with commercially available endoscopes with a minimum working channel inner diameter (ID) of 3.7 mm and maximum length of 100 cm. The subject Catheter is part of a cryosurgical system comprised of three components including a Catheter (sterile, single use), Controller (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 is 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.

V. INDICATIONS FOR USE

The C2 CryoBalloon™ Focal Ablation System is intended to be used as a cryosurgical tool for the destruction of unwanted tissue in the field of general surgery, specifically for endoscopic applications.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Cryoablation is the fundamental technological principle for both the subject C2 CryoBalloon™ Focal Ablation System and the predicate CryoBalloon Focal 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™ Focal Ablation System has similar technological characteristics to the legally marketed predicate. The subject device and predicate device are based on the following same technological elements:

- Inserted through an endoscope to access the treatment site
- Apply a 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) activates release of the cryogen
- Battery-operated Controller and software

The only modifications that were made include:

- The Catheter was modified to a different shaped balloon.
- The distal Catheter tip was modified to reduce the length.
- The proximal Catheter connector cryogen inflow tubing was modified to change the tubing material.
- The product name was changed slightly.

VII. PERFORMANCE DATA

Performance data were provided in support of the substantial equivalence determination. Design verification testing, based on results of risk analysis, was performed on the C2 CryoBalloon™ Focal Ablation System to evaluate the physical, reliability, and safety specifications. The testing performed includes dimensional verification, balloon integrity, balloon fatigue, and bond and connector tensile strength and integrity.

VIII. CONCLUSION

The subject C2 CryoBalloon™ Focal Ablation System has the same clinical attributes, technological characteristics, and expected performance as the legally marketed predicate, CryoBalloon Focal Ablation System (K131523). The performance data results demonstrate that the subject C2 CryoBalloon™ Focal Ablation System should perform as intended in the specified use conditions and should perform comparably to the legally marketed predicate that is currently marketed for the same intended use.