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

January 23, 2018

C2 Therapeutics, Inc.
Patrick Wu
Director of Research and Development
303 Convention Way, Ste. 1
Redwood City, CA 94063

Re: K163684
Trade/Device Name: C2 Cryoballoon Ablation System
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryogenic unit and accessories
Regulatory Class: Class II
Product Code: GEH
Dated: December 21, 2017
Received: December 22, 2017

Dear Patrick Wu:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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 -S3

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)*
K163684

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.

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K163684

510(k) Summary

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

I. SUBMITTER

C2 Therapeutics, Inc.
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Redwood City, CA 94063

Phone: 408-368-6043

Fax: 650-556-1145

Contact Person: Patrick Wu
Director of Research and Development

Date Prepared: January 23, 2018

II. DEVICE

Name of Device: C2 CryoBalloon™ Ablation System (subject 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 Devices: Primary:
C2 Therapeutics, Inc. (K161202)
C2 CryoBalloon™ Ablation System

Secondary:
C2 Therapeutics, Inc. (K152329)
Coldplay CryoBalloon™ Focal Ablation System
Coldplay CryoBalloon™ Full Ablation System
Coldplay CryoBalloon™ Swipe Ablation System

IV. DEVICE DESCRIPTION

The C2 CryoBalloon Ablation System is a cryosurgical device, which consists of four (4) components: (i) a single-use, sterile balloon Catheter that is inserted through the working channel of an endoscope with a minimum inner diameter (ID) of 3.7 mm and a maximum working length of 100 cm; (ii) a hand-held reusable Controller with a liquid crystal display (LCD) touch screen interface; (iii) a reusable Foot Pedal that is plugged into mains, provides power for the Controller, and allows the user to operate system functions such as ablation targeting, nitrous oxide flow control, and balloon deflation; and (iv) single-use Nitrous Oxide Cartridge that provides users with cryogen for each treatment.

The C2 CryoBalloon Ablation System uses nitrous oxide as a cryogen to cause necrosis of targeted tissue in a controlled manner. The low operating pressure inflates the compliant balloon against the lumen ID. Nitrous oxide is directed at the targeted tissue and it evaporates on the inner surface of the balloon and freezes the tissue. The nitrous oxide is fully contained within the balloon and the resultant gas exhausts through the Catheter shaft and vents through the Controller.

There are four (4) Catheter configurations that distribute nitrous oxide focally (focal diffuser), over a quarter of the lumen circumference (90° diffuser), over half of the lumen circumference (180° diffuser), or over the full circumference of the lumen (360° diffuser). The user selects the Catheter with the desired diffuser type, removes it from the sterile packaging and inserts it through the working channel of an endoscope until the balloon portion exits the distal end of the endoscope.

The connector portion of the Catheter is inserted into the Controller and the radiofrequency identification (RFID) communication system in the Catheter connector and the Controller allows the Controller to perform functions specific to the Catheter. The LCD touch screen allows the user to set desired dosimetry, and communicates system status to the user.

The user tightens the Controller Cap against the Controller, which pierces the nitrous oxide Cartridge. Nitrous oxide is contained in the Controller until the user steps on the Foot Pedal to allow the Controller to release it into the Catheter. The user visualizes the targeting and ablation via the inflated balloon and the images provided by the endoscope. The balloon is held in contact with the treatment area during the ablation. Upon conclusion of the procedure the balloon is deflated and withdrawn into the endoscope.

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 devices are based on the same endoscopic instrumentation for accessing targeted sites and visualization.

The subject device has the same Indications for Use as the predicate devices.

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

- Inserted through an endoscope to access the treatment site
- Application of nitrous oxide cryogen to ablate (freeze) the targeted tissue
- Use of direct visualization to the treatment area
- Use of a compliant balloon to position the treatment
- Use of a balloon to contain the cryogen (gas does not contact tissue)
- Use of the Catheter shaft to vent gas out of patient
- Use of diffuser to direct cryogen on targeted tissue
- User-controlled release of cryogen
- Software activated Controller

The Controller is reused after intermediate level cleaning and disinfection.

VII. PERFORMANCE DATA

Performance Data were provided for the C2 CryoBalloon Ablation System and its components in support of substantial equivalence determination. The following was performed on the subject C2 CryoBalloon Ablation System to evaluate physical reliability, safety, and effectiveness.

Testing Type	Objectives	Results

Bench Testing	The nonclinical testing assessed functional performance of the system. The following describes the key aspects of the device that were tested:
	• Simulated Use
	  o Verify temperature uniformity and depth of penetration during cryogen application.
	  o Verify system hold pressure is maintained with no leakage.
	  o Verify controller reliability after 1-year of reuse.
	• Dimensional Testing
	  o Verify balloon and Catheter dimensions
	  o Verify Catheter able to pass through 3.7mm or larger accessory channel.
	• Mechanical Integrity
	  o Verify rated burst pressure of balloon is sufficiently greater than nominal operating pressure
	  o Tensile test all of the Catheter bonds
	  o Verify balloon reliability after repeated inflations
		The subject C2 CryoBalloon Ablation System passed all functional testing and met all product specification requirements.

Software	Perform testing to verify conformance to Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, Guidance for Industry and FDA Staff, May 11, 2005.	The subject C2 CryoBalloon Ablation System met all software test requirements for software with a Major Level of Concern.
Electrical Safety	Perform testing to verify conformance to the following standards: • ES 60601-1:2005/(R)2012 And A1:2012 • IEC 60601-1-2:2007 • IEC 60601-1-6 Edition 3.1 2013-10	The subject C2 CryoBalloon Ablation System met the electrical safety, electromagnetic compatibility, and coexistence test requirements and is fully compliant with all of the listed standards.

Testing Type	Objectives	Results
Controller Reprocessing	Perform testing to verify conformance to Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and FDA Staff, March 17, 2015. Perform microbial ingress testing to confirm contaminated (interior and exterior) Controller does not cross-contaminate the Catheter.	The subject C2 CryoBalloon Controller's intermediate level cleaning and disinfection processes have been validated per FDA guidance. The microbial ingress testing demonstrated that a contaminated Controller does not cross-contaminate the Catheter; therefore, Intermediate Level Cleaning and Disinfection are appropriate reprocessing processes for the subject device.
Biocompatibility	Perform testing to verify conformance to the following standards: • Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process," Guidance for Industry and FDA Staff, June 16, 2016 • ISO 10993-1:2009 • ISO 10993-5:2009 • ISO 10993-10:2010	The subject C2 CryoBalloon Ablation System met the cytotoxicity, irritation, and sensitization requirements. The subject device materials are the same as the predicate devices.
Catheter Sterilization	Perform testing to verify conformance to the following standards: • ISO 11135:2014 • ISO 10993-7:2008	The subject C2 CryoBalloon Catheter met the sterilization and residuals requirements. The subject Catheter sterilization is the same as the predicate Catheters.

Testing Type	Objectives	Results
Packaging/Shelf Life	Perform testing to verify conformance to the following standards: • ISO 11607-1:2006 (Catheter only) • ASTM D4332-14 • ASTM D4169-14 • ASTM F2096-11 (Catheter only) • ASTM F88-15 (Catheter only) • ASTM F1929-15 (Catheter only)	The subject C2 CryoBalloon Ablation System met the packaging test requirements.
Usability	Perform testing to verify conformance to Applying Human Factors and Usability Engineering to Medical Devices, Guidance for Industry and FDA Staff, February 3, 2016.	The subject C2 CryoBalloon Ablation System was found to be safe and effective for the intended user, uses, and use environment. Residual risks do not require device modification.

VIII. CONCLUSIONS

The subject C2 CryoBalloon™ Ablation System (K163684) has the same intended use and indications for use as the predicate C2 CryoBalloon™ Ablation Systems (K161202). The preclinical bench performance data supports the indication for use and demonstrates that the subject device is as safe, effective, and performs as well as the predicate device. The subject device has the equivalent technological characteristics and performance data to support substantial equivalence in terms of safety and effectiveness.