DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 7, 2015

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

Re: K151054
Trade/Device Name: Coldplay Full CryoBalloon Ablation System, Coldplay Swipe CryoBalloon Ablation System
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: Class II
Product Code: GEH
Dated: June 10, 2015
Received: June 11, 2015

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" (21CFR 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 -S

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)*

K151054

Device Name

Coldplay Full CryoBalloon Ablation System, Coldplay Swipe CryoBalloon Ablation System

Indications for Use *(Describe)*

The Coldplay CryoBalloon 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.

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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

Submitter Name: C2 Therapeutics, Inc.

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Phone Number: 650-521-5921

Fax Number: 650-556-1145

Contact Person: Theresa Brandner-Allen
VP of Regulatory Affairs and Quality Assurance

Date Prepared: July 06, 2015

II. DEVICE

Name of Device: Coldplay Full CryoBalloon Ablation System and
Coldplay Swipe 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

K131523, Cryoballoon Focal Ablation System

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

IV. DEVICE DESCRIPTION

The modified device is a cryosurgical unit with a nitrous oxide cooled balloon probe that is intended for use with commercially available endoscopes with a minimum working

channel inner diameter (ID) of 3.7 mm. It is comprised of three components including a Catheter (sterile), Handle (non-sterile), and Cartridge (non-sterile).

The modified device is used to destroy unwanted tissue by application of extreme cold to either a 360° circumference or a 90° circumference. The balloon probe at the end of the catheter is inflated with nitrous oxide gas and comes in contact with tissue. Tissue is visualized through the pre-inflated balloon, and the treatment site is selected is by manipulation of the endoscope and Handle. The liquid nitrous oxide spray ablates the unwanted tissue. Nitrous oxide is fully contained within the balloon probe and does not directly contact the tissue. The nitrous oxide gas exits the patient through the Catheter lumen and exhausts out the Handle.

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

V. INDICATIONS FOR USE

The Coldplay CryoBalloon 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 modified Coldplay CryoBalloon Ablation System and the predicate CryoBalloon Focal Ablation System. Both the modified device and predicate device are based on the same endoscopic instrumentation for removing unwanted tissue using extreme cold.

The modified Coldplay CryoBalloon Ablation System has similar technological characteristics to the legally marketed predicate. The modified 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 Handle controller and software

The only modifications that were made include:

- The cryogen diffuser was changed from a focal spray a circumferential spray that traverses during treatment
- The Handle software and catheter interface were modified to accommodate the circumferential spray
- The cryogen cylinder was changed to a larger cylinder to accommodate the

circumferential spray

VII. PERFORMANCE DATA

Performance data were provided in support of the substantial equivalence determination including. Design verification and validation testing were performed on the Coldplay CryoBalloon Ablation System to evaluate physical, simulated use, reliability, safety, biocompatibility, sterilization, and shelf life specifications. Software verification and validation were performed.

VIII. CONCLUSION

The modified Coldplay CryoBalloon 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 Coldplay CryoBalloon 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.