



Food and Drug Administration
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April 13, 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: K152329

Trade/Device Name: Coldplay Cryoballoon™ Focal Ablation System;
Coldplay Cryoballoon™ Full Ablation System;
Coldplay Cryoballoon™ Swipe Ablation System

Regulation Number: 21 CFR 878.4350

Regulation Name: Cryogenic unit and accessories

Regulatory Class: Class II

Product Code: GEH

Dated: March 07, 2016

Received: March 08, 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 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 -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

Indications for Use

510(k) Number (if known)

K152329

Device Name

Coldplay CryoBalloon™ Focal Ablation System, Coldplay CryoBalloon™ Full Ablation System, Coldplay CryoBalloon™ Swipe Ablation System

Indications for Use (Describe)

The Coldplay CryoBalloon™ Focal Ablation System, Coldplay CryoBalloon™ Full Ablation System, and Coldplay CryoBalloon™ Swipe Ablation System are 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 high grade 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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K152329 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: April 12, 2016

II. DEVICE

Name of Device: Coldplay CryoBalloon™ Focal Ablation System
Coldplay CryoBalloon™ Full Ablation System
Coldplay CryoBalloon™ Swipe 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 DEVICES

Coldplay CryoBalloon™ Ablation System: K131523, K151054
CSA Medical truFreeze: K143625
Barrx HALO: K083737

CSA Medical has reported two design-related recalls for the truFreeze device. Barrx Medical has reported three design-related recalls for the HALO device. The

Coldplay CryoBalloon™ Ablation System predicate devices have not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The subject device is a cryosurgical system 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 length of 100 cm. The subject device is a system comprised of three components including a Catheter (sterile), Handle (non-sterile), and Cartridge (non-sterile).

The subject device is used to ablate unwanted tissue by application of extreme cold to a 360° circumference, 90° circumference, or 45° circumference and is identical to the respective Coldplay CryoBalloon™ Ablation System predicates. 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 by adjusting the endoscope and Handle. The nitrous oxide spray cools the balloon to ablate the unwanted tissue, and the nitrous oxide exhausts through the Handle.

V. INDICATIONS FOR USE

The Coldplay CryoBalloon™ Focal Ablation System, Coldplay CryoBalloon™ Full Ablation System, and Coldplay CryoBalloon™ Swipe Ablation System are 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 high grade dysplasia.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Cryoablation is the fundamental technological principle for both the subject Coldplay CryoBalloon™ Focal Ablation System, Coldplay CryoBalloon™ Full Ablation System, and Coldplay CryoBalloon™ Swipe Ablation System and the predicate Coldplay CryoBalloon™ Ablation Systems and the predicate CSA Medical truFreeze. Both the subject device and all predicate devices are used as endoscopic instrumentation for ablating unwanted tissue.

The only modification to the subject device is to update the labeling to modify the indication for use to list treatment of Barrett's Esophagus and to include the treatment parameters, similar to the indications for use and treatment parameter type updates made by the predicate devices and to reflect physician use. The subject device has similar technological characteristics to the legally marketed predicates. The subject device and predicate devices are based on the following same technological elements:

- Inserted through an endoscope to access the treatment site
- Apply extreme temperature (cryogen or heat) to ablate (freeze or cauterize) the unwanted tissue
- Use of a compliant balloon to position the treatment diffuser
- User-controlled activation to release and apply the therapy
- Software controlled

There have been no technological changes to the subject device, and there are no technological differences between the subject device and predicate devices. The subject device remains substantially equivalent to the predicate devices.

Per Section III, design-related recalls for the CSA Medical truFreeze predicate^{1, 2} and Barrx Medical HALO predicate^{3, 4, 5} have been reported. The Coldplay CryoBalloon™ Ablation System predicate devices have not been subject to a design-related recall.

VII. PERFORMANCE DATA

Because there have been no technological changes to the subject device, no additional bench testing, preclinical testing, sterilization, and biocompatibility testing was performed.

A clinical study was performed to support the modification of the indications for use to include ablation of Barrett's Esophagus with high grade dysplasia. The study conducted was prospective, multicenter clinical data for 37 patients with Barrett's Esophagus. There were a total of 56 focal ablations performed in 37 patients. For the 56 ablations performed, the duration of the ablation was 6 seconds (n=10), 8 seconds

¹ Recall number Z-1513-2015 was conducted due to active and passive venting during the procedure. Because the Coldplay CryoBalloon Ablation System fully contains the cryogen during the procedure, active or passive venting is not required, and this design malfunction or potential patient injury is not relevant to the Coldplay CryoBalloon Ablation System. This recall has been terminated.

² Recall number Z-0941-2015 was conducted due to an increase in complaint trending for a loss of audible sound associated with the timer. The software with audible sounder used in the Coldplay CryoBalloon Ablation System has been validated, and this design malfunction has not been observed with the Coldplay CryoBalloon Ablation System. This recall has been terminated.

³ Recall number Z-2745-2011 was conducted due device pivot mechanism's inability to return the electrode cap to a flat neutral position. Because the Coldplay CryoBalloon Ablation System's diffuser is fully contained within the balloon during the procedure, this design malfunction is not relevant to the Coldplay CryoBalloon Ablation System. This recall has been terminated.

⁴ Recall number Z-0192-2009 was conducted because some units may contain the wrong filter, which does not have the proper lock and may result in a leak. The Coldplay CryoBalloon Ablation System does not have a filter, and this design malfunction is not relevant to the Coldplay CryoBalloon Ablation System. This recall has been terminated.

⁵ Recall number Z-2379-2012 was conducted due to a potential failure of HALO Energy Generator to enter "stand by" mode when initially powered on prior to use on the patient. The software used in the Coldplay CryoBalloon Ablation System has been validated, and this design malfunction has not been observed with the Coldplay CryoBalloon Ablation System. This recall has been terminated.

(n=28), or 10 seconds (n=18). No patients required any further interventions. Pain in the treatment area immediately post procedure was reported in 10 patients (27%) with median score of 2.5 (IQR 2-3). None of these patients required additional pain medication. At 2 days post-procedure, 5 patients (14%) reported pain in the treatment area with a median score of 4 (IQR 3-6) and pain when swallowing with median score of 4 (IQR 2-5). In the days following the ablation procedure, 3 patients (8%) used additional pain medication. There were no serious adverse events reported. At the time of follow-up endoscopy, full conversion of Barrett's epithelium to neosquamous epithelium was observed significantly more frequently in 6 (60%) of the 6-second ablations, 23 (82%) of the 8-second ablations, and 18 (100%) of the 10-second ablations (P=0.04). Conversion was confirmed through biopsy. During the follow-up period, no adverse events occurred. The clinical study results indicate, when used in accordance with the Instructions for Use, the subject device is effective at demonstrating complete response of high grade dysplasia at follow-up. The subject device prospective clinical study data and other published literature data indicate it is at least as safe and effective as the legally marketed predicates for ablation of Barrett's Esophagus with high grade dysplasia. The clinical performance data support the indication for use modification and the substantial equivalence determination.

VIII. CONCLUSION

The subject Coldplay CryoBalloon™ Focal Ablation System, Coldplay CryoBalloon™ Full Ablation System, and Coldplay CryoBalloon™ Swipe Ablation System are substantially equivalent to predicate devices. Use of the Coldplay CryoBalloon™ Focal Ablation System, Coldplay CryoBalloon™ Full Ablation System, and Coldplay CryoBalloon™ Swipe Ablation System for treatment of Barrett's Esophagus for ablation of high grade dysplasia is supported by a clinical study and performance data derived from literature.