DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

April 14, 2015

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

Re: K150083
Trade/Device Name: Sidecar External Working Channel
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FED
Dated: March 13, 2015
Received: March 16, 2015

Dear Theresa 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,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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)*
K150083

Device Name
Sidecar External Working Channel

Indications for Use *(Describe)*
The Sidecar External Working Channel is an external channel for an endoscope (8.6 to 12.8 mm in diameter) used to aid in the insertion, advancement, and removal of endoscopic devices during endoscopic procedures.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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

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: January 12, 2015

II. DEVICE

Name of Device: Sidecar External Working Channel, endoscopic access overtube
Common Name: Endoscopic access overtube, gastroenterology-urology
Classification Name: Endoscopic access overtube, gastroenterology-urology
21 CFR§876.1500
Regulatory Class: Class II
Product Code: FED

III. PREDICATE DEVICE

EndoFLIP External Channel Device (EF-800), K110531
This predicate has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The Sidecar External Working Channel is an external channel for an endoscope used for inserting, advancing, and removing endoscopic devices during endoscopic procedures. It is supplied non-sterile and is intended to be a single-patient use device. It is designed to work with upper gastrointestinal diagnostic endoscopes with an outer diameter from 8.6 mm to 12.8 mm. It is attached to the distal and proximal ends of an endoscope and inserted with the endoscope.

V. INDICATIONS FOR USE

The Sidecar External Working Channel is an external channel for an endoscope (8.6 to 12.8 mm in diameter) used to aid in the insertion, advancement, and removal of endoscopic devices during endoscopic procedures.

Patient Population: Patients undergoing endoscopic procedures

Environment of Use: Hospitals, sub-acute care institutions, surgery centers, or doctor's office where endoscopic procedures may be performed

Contraindications: The Sidecar External Working Channel is contraindicated where endoscopy is contraindicated

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Sidecar External Working Channel has similar technological characteristics to the legally marketed predicate. The subject device and predicate device are based on the following same technological elements:

- Attached over an endoscopic device to provide an external working channel
- Aids in the insertion, advancement, and removal of the endoscopic accessories during endoscopic procedures
- Used in hospitals, sub-acute care institutions, surgery centers, or doctor's office where endoscopic procedures may be performed
- Used for patients undergoing endoscopic procedures

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

- Attachment and removal from the endoscope does not require use of a tool
- Compatible with a wider range of endoscope diameters

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

Biocompatibility testing was performed in accordance with the FDA Blue Book Memorandum #G95-1 *Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing* and ISO 10993-1 *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process*.

Bench Testing

Design verification and validation testing were performed on the Sidecar External Working Channel to evaluate physical, simulated use, reliability, and safety specifications.

VIII. CONCLUSION

The Sidecar External Working Channel has the same clinical attributes, technological characteristics, and expected performance as the legally marketed predicate, EndoFLIP External Channel Device (K110531). The design verification and validation test results demonstrate that the Sidecar External Working Channel 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.