



Food and Drug Administration
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October 13, 2015

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

Re: K152140
Trade/Device Name: Boa Endoscopic Valve
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCX
Dated: September 24, 2015
Received: September 25, 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

Indications for Use

510(k) Number (if known)
K152140

Device Name

Boa Endoscopic Valve™

Indications for Use (Describe)

The Boa Endoscopic Valve™ is intended to provide access for endoscopic device passage and exchange throughout the endoscopic procedure.

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

Submitter Name: C2 Therapeutics, Inc.

Address: 303 Convention Way, Suite 1
Redwood City, CA 94063

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 30, 2015

II. DEVICE

Name of Device: Boa Endoscopic Valve™

Common Name: Endoscopic valve

Classification Name: Endoscope and accessories, 21 CFR§876.1500

Regulatory Class: Class II

Product Code: OCX

III. PREDICATE DEVICE

EndoChoice Seal Biopsy Valve, K111821

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

IV. DEVICE DESCRIPTION

The Boa Endoscopic Valve™ is used with endoscopes and endoscopic devices with a maximum outer diameter up to 0.167 in. Endoscopic devices are inserted through the Boa Endoscopic Valve™ and through the endoscope. The Boa Endoscopic Valve™ forms a seal around endoscopic devices, supports the endoscopic device, and maintains the position relative to the endoscope biopsy channel port. It is compatible with biopsy port valves and is positioned against the biopsy valve of the endoscope. The Boa Endoscopic Valve™ is non-sterile and is designed for single patient use.

V. INDICATIONS FOR USE

The Boa Endoscopic Valve™ is intended to provide access for endoscopic device passage and exchange throughout the endoscopic procedure.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Boa Endoscopic Valve™ has similar technological characteristics to the legally marketed predicate. The subject device and predicate device are based on the following same technological elements:

- Attached to the proximal biopsy channel port of an endoscopic device to provide endoscopic device passage and exchange
- Aids in the insertion, use, and removal of the endoscopic accessories during endoscopic procedures
- Minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure
- Used in hospitals, sub-acute care institutions, surgery centers, or doctor's office where endoscopic procedures may be performed
- Used in a single patient (disposable) undergoing endoscopic procedures

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

- The top of the modified device is rotated during use, and the top of the predicate device is pulled up during use

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 Boa Endoscopic Valve™ to evaluate physical, simulated use, reliability, and safety specifications.

VIII. CONCLUSION

The Boa Endoscopic Valve™ has the same clinical attributes, technological characteristics, and expected performance as the legally marketed predicate, EndoChoice Seal Biopsy Valve (K111821). The design verification and validation test results demonstrate that the Boa Endoscopic Valve™ 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.