510(K) SUMMARY

[as required by section 807.92(c)]

Bonastent® Biliary

510(k) Number K140760

Prepared on (revised):
April 10, 2014

Applicant's Name:
EndoChoice Inc.
11800 Wills Rd., Suite 100
Alpharetta, GA 30009
Telephone: 678-534-6021
Fax: 770-410-9008

Contact Person:
Bosmat Friedman
CO/MJ RAC
1208-12 Rockford Rd. Toronto, ON, M2R 3A2,
Canada
Phone: 647-975-3974
Fax: 647-427-1946
E-mail: bosmat@pushmed.com

Trade Name:
Bonastent® Biliary

Classification Name:	catheter, biliary, diagnostic
Regulation Number:	876.5010
Product Code:	FGE
Classification:	Class II
Review Panel:	Gastroenterology/Urology

Predicate Devices:
BONASTENT® Biliary by EndoChoice Inc., K093003

Device Description:
The Bonastent® Biliary stent is a self-expanding polygon mesh surface, tubular prosthesis designed to maintain patency of bile duct strictures caused by malignant tumors. The stent is made of Nitinol wire and is designed in such a way as to prevent migration and tumor in-growth. The stent is provided preloaded on a delivery device and is available in 2 different diameters (8mm and 10mm) in various lengths.

Reason for Submission:
Material changes to delivery device.

Intended Use:

The Bonastent® Biliary is indicated for the palliation of malignant strictures in the biliary tree.

Technological Characteristics:

The Bonastent® Biliary is weaved using hook & cross wire construction which reduces the delivery device diameter. The stent includes 3 groups of 4 radiopaque markers located at the center of the stent as well as at both ends of the stent.

The reason for this 510(k) submission is material changes in the delivery device.

Verification & Validation Activities:

Biocompatibility and bench tests were performed in order to ensure that the material changes do not affect the device performance. The results of Cytotoxicity, Sensitization and Irritation tests as well as deployment and tensile strength testing support our claim that the device is safe and effective.

Substantial equivalence:

BONASTENT® Biliary has been previously cleared by the agency under K093003. The only difference between the original cleared device and the subject of this submission are material changes that have been incorporated into the delivery device to enhance deployability and to make the manufacturing process more efficient. The performance and biocompatibility profile of the device have been evaluated; the results support that no new safety and effectiveness issues are raised due to the changes.

Conclusion:

EndoChoice believes that, based on the information provided in this submission, the Bonastent® Biliary stent system is substantially equivalent to its predicate devices without raising any new safety and/or effectiveness issue.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 16, 2014

EndoChoice, Inc.
% Bosmat Friedman
Regulatory Consultant
MJ RAC
1208-12 Rockford Road
Toronto, ON M2R 3A2
Canada

Re: K140760
Trade/Device Name: BONASTENT® Biliary
Regulation Number: 21 CFR§ 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: April 14, 2014
Received: April 15, 2014

Dear Bosmat Friedman,

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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings device's labeling:

The safety and effectiveness of this device for use in the performance of the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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" (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 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,

Christy L. Foreman -S

Christy Foreman
Director
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)*
K140760

Device Name
BONASTENT® Biliary

Indications for Use *(Describe)*
The BONASTENT® Biliary Stent is indicated for the palliation of malignant strictures in the biliary tree.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Herbert P. Lerner -S
2014.06.16 15:18:29 -04'00'

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."