510(K) SUMMARY

[as required by section 807.92(c)]

Bonastent® Biliary

510(k) Number K 093003

MAR 24 2010

Applicant's Name:
EndoChoice Inc.
11800 Wills Rd.
Suite 100Alpharetta, GA 30009
Telephone: 770-682-8700
Fax: 770-962-6981

Contact Person:
Name: Shoshana (Shosh) Friedman
Telephone: 704-899-0092
Fax: 704-899-0098
Email: shosh@pushmed.com

Trade Name:
Bonastent® Biliary

Classification Name:	Biliary catheter and accessories
Regulation Number:	876.5010
Product Code:	FGE
Classification:	Class II
Review Panel:	Gastroenterology/Urology

Predicate Devices:
- Niti-S Biliary Stent by Taewoong Medical Co., Ltd, K073667
- WallFlex™ Biliary RX Stent System by Boston Scientific Corporation K081733

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.

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.

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 Room W-O66-0609
Silver Spring, MD 20993-0002

MAR 2 4 2010

Ms. Shoshana Friedman, RAC
Regulatory Consultant
EndoChoice, Inc.
11800 Wills road, Suite 100
ALPHARETTA GA 30009

Re: K093003
Trade/Device Name: BONASTENT® Biliary Stent
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: March 16, 2010
Received: March 18, 2010

Dear Ms. 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.

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 section of the device's labeling:

> The safety and effectiveness of this device for use in 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); 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 information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (301) 796-5484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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) 796-5857 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zimmerman for

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093003

Device Name: BONASTENT® Biliary Stent

Indications For Use: The BONASTENT® Biliary Stent is indicated for the palliation of malignant strictures in the biliary tree.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K093003