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SECTION 5: 510(k) SUMMARY

A. Submitter Information

Submitter's Name:	Ostial Corporation
Address:	510 Clyde Avenue Mountain View, CA 94043
Telephone:	650-903-9100
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Email:	kvonhoffmann@ostialcorp.com
Contact Person:	Kaitlin von Hoffmann
Date of Preparation:	November 30, 2011

JUN 2 9 2012

B. Subject Device

Trade Name:	ArchStent Biliary System
Common/Usual Name:	Biliary Stent
Classification Name:	Biliary Catheter
Product Code:	FGE; Catheter, Biliary, Diagnostic per 21 C.F.R. 876.5010

C. Device Description:

The ArchStent Biliary System is a 0.014" guidewire-compatible, rapid exchange (RX) balloon-expandable stent system. It consists of a stainless steel stent that can flare in the proximal segment and a dual balloon delivery catheter. Accessories include a 1.0 cc Syringe and a 10 cc Deflation Syringe.

D. Intended Use:

The ArchStent Biliary System is intended for use in the palliation of malignant neoplasms in the biliary tree.

E. Summary of Similarities and Differences in Technological Characteristics, Performance and Intended Use:

The ArchStent Biliary System is a modified version of the BullsEye Biliary Stent System, which was cleared via 510(k) #K082093 on July 29, 2009. Minor design changes were implemented to improve usability and offer additional stent diameters and catheter lengths. A table describing the differences between the two versions is included in **Section 12** of this submission.

F. Performance Data:

Biocompatibility testing for the intended application of the device was performed as suggested by the International Standards Organization (ISO) 10993 Guidelines, FDA General Program Memorandum No. G95-1, the Office of Device Evaluation (ODE) Bluebook Memorandum, No. G95-1 "Use of ISO-10993 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing," and the FDA guidance document "Guidance for the Content of Premarket Notifications for Metal Expandable Biliary Stents," February 1998. The final results of the biocompatibility tests on the ArchStent Biliary System demonstrated that the device is biocompatible for the intended use. A summary of the testing can be found in **Section 19** of this submission.

To demonstrate conformance to its product specifications, the ArchStent Biliary System was further evaluated using the following in-vitro performance bench tests:

- Deployment Testing
- Compression Force Testing
- Dimensional Testing
- Corrosion Testing
- Balloon Performance Testing
- Stent Deformation Testing
- Tensile Strength Testing

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All testing was performed on sterile, finished devices per the FDA guidance document "Guidance for the Content of Premarket Notifications for Metal Expandable Biliary Stents," February 1998.

G. Conclusions:

The ArchStent Biliary System is intended for use in the palliation of malignant neoplasms in the biliary tree. The device is a modified version of the BullsEye Biliary Stent System, which was cleared via 510(k) #K082093 on July 29, 2009. All test results demonstrate that the materials, manufacturing process, and the design of the ArchStent Biliary System meet the established specifications necessary for consistent performance according to its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Ms. Kaitlin von Hoffmann
Clinical and Regulatory Associate
Ostial Corporation
510 Clyde Avenue
MOUNTAIN VIEW CA 94043

JUN 29 2012

Re: K113582
Trade/Device Name: ArchStent Biliary System
Regulation Number: 21 CFR§ 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: June 21, 2012
Received: June 25, 2012

Dear Ms. von Hoffmann:

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); 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

for Christy Foreman
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113582

Device Name: ArchStent Biliary System

Indications For Use: The ArchStent Biliary system is intended for use in the palliation of malignant neoplasms in the biliary tree

Prescription Use ___X___ 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, Gastro-Renal, and Urological Devices
510(k) Number K113582