Ostial Corporation
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JUL 02 2014

510(k) Summary
FLASH Ostial System OTW

A. Submitter Information

Submitter's Name:	Ostial Corporation
Address:	1221 Innsbruck Drive Sunnyvale, CA 94089
Telephone:	408-541-1006
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Email:	jwolenberg@ostialcorp.com
Contact Person:	Jake Wolenberg
Date of Preparation:	December 18, 2013

B. Subject Device

Proprietary Name:	FLASH Ostial System OTW
Common/Usual Name:	Balloon Catheter
Classification Name:	Catheter, Angioplasty, Peripheral, Transluminal
Product Code:	LIT per 21 C.F.R. 870.1250

C. Predicate Device Name

Proprietary Name:	FLASH Ostial System (a.k.a. Flash PTA Balloon Dilatation Catheter; Flash Ostial Balloon PTA)
510(k) #'s:	K102482, K120738, K121175, and K122379
Common/Usual Name:	Balloon Catheter
Classification Name:	Catheter, Angioplasty, Peripheral, Transluminal
Product Code:	LIT per 21 C.F.R. 870.1250

D. Device Description:

The Flash Ostial System OTW is designed for the dilatation of stenotic ostial lesions in the peripheral vasculature. The FLASH Ostial System OTW is a 0.035" guidewire-compatible, over the wire (OTW) angioplasty balloon catheter with proximal anchoring and a working length of either 80cm or 135cm. The FLASH Ostial System OTW uses a dual balloon design that features a compliant anchoring balloon, which prevents distal migration of the balloon during angioplasty. The second semi-compliant higher-pressure balloon allows for luminal dilatation of *de novo* lesions and post deployment stent expansion.

E. Intended Use:

The Flash Ostial System OTW is indicated for Percutaneous Transluminal Angioplasty in the peripheral vasculature at aorto-ostial locations, including iliac, renal and carotid arteries. This device is also indicated for post-dilatation of balloon expandable stents in the peripheral vasculature.

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

The FLASH Ostial System OTW that is the subject of this 510(k) is an extension of the FLASH Ostial System product line. The Flash Ostial System OTW shares the same basic catheter design as the currently cleared versions of the Flash Ostial System. Both versions of the device utilize a dual balloon design featuring an Anchoring Balloon that enables the operator to position the catheter at aorto-ostial anatomies and prevents distal migration of the balloon during angioplasty. Additionally, the Indications for Use for both versions of the device are exactly the same. There are, however, some minor design differences between the Flash Ostial System OTW and the currently cleared Flash Ostial System. These differences are summarized below.

- Whereas the Flash Ostial System is designed to be compatible with 0.014" diameter guidewires, the Flash Ostial System OTW is designed to be compatible with 0.035" diameter guidewires.

- Whereas the Flash Ostial System is designed to be a rapid exchange platform, the Flash Ostial System OTW is designed to be an over the wire platform.

- Whereas the Flash Ostial System is compatible with 6F and 7F guide catheters, the Flash Ostial System OTW is compatible with 6F and 7F guide sheaths.

- Whereas the Flash Ostial System is only offered with only one catheter length, 135cm, the Flash Ostial System OTW will be offered in two catheter lengths, 135cm and 80cm. The only difference between the 135cm and 80cm version of the device is the length of the catheter shaft.

Note: The proprietary name for the previous 510(k)'s filed for this product line was "Flash PTA Balloon Dilatation Catheter". Following clearance of the 510(k)'s, the proprietary name was modified for better market positioning. The device is currently marketed under the proprietary name "FLASH Ostial System". The line extension devices are intended to be marketed under the proprietary name "FLASH Ostial System OTW".

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G. Performance Data:

Biocompatibility testing has previously been completed on product equivalent to the FLASH Ostial System OTW. Requirements for biological evaluation of the proposed device were based on the Blue Book Memorandum issued on May 1, 1995, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing." and the current FDA recognized standard ISO 10993-1: Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process. The biocompatibility test results show that the materials used in the design and manufacture of the components of the proposed device are non-toxic and non-sensitizing to biological tissues consistent with its intended use. The following biocompatibility tests were completed:

- ISO MEM Elution Assay
- ASTM Hemolysis Assay
- Complement Activation C3a and SC5b-9 Assay
- Thromboresistance Evaluation
- Materials Mediated Rabbit Pyrogen
- ISO Guinea Pig Maximization Sensitization
- ISO Acute Systemic Injection Test
- ISO Intracutaneous Reactivity Test
- Pyrogen (LAL) Chromogenic

The FLASH Ostial System OTW or product equivalent was evaluated using the following in-vitro and performance bench testing to confirm the performance characteristics as compared to the product performance requirements:

- Balloon Crossing Profile
- Catheter Shaft Diameter
- Catheter Working Length
- Catheter Inner Diameter
- Angioplasty Balloon Rated Burst Pressure
- Anchoring Balloon Burst Volume
- Angioplasty Balloon Compliance
- Balloon Inflation Time
- Balloon Deflation Time
- Angioplasty Balloon Rated Burst Pressure (in Stent)
- Anchoring Balloon Burst Volume (in Stent)
- Angioplasty Balloon Fatigue
- Anchoring Balloon Fatigue
- Catheter Bond Strength
- Catheter Tip Pull Strength
- Catheter Torque Strength
- Simulated Use
- Flexibility and Kink Resistance
- Radiopacity
- Angioplasty Balloon Fatigue (in Stent)
- Anchoring Balloon Fatigue (in Stent)

All test results demonstrate that the FLASH Ostial System OTW meets the established product specifications.

H. Conclusions:

All test results demonstrated that the FLASH Ostial System OTW meets all predetermined design verification and validation acceptance criteria necessary to verify safe and consistent performance of the device for its Indications for Use in *"Percutaneous Transluminal Angioplasty in the peripheral vasculature at aorto-ostial locations, including iliac, renal and carotid arteries"* and *"post-dilatation of balloon expandable stents in the peripheral vasculature."* As such, Ostial Corporation is requesting clearance for the FLASH Ostial System OTW product line extension to the FLASH Ostial System product family, which was most recently cleared via Premarket Notification 510(k) # K122379 on September 5, 2012.

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

July 2, 2014

Ostial Corporation
Mr. Jake Wolenberg
Quality Assurance and Regulatory Affairs Manager
1221 Innsbruck Drive
Sunnyvale, CA 94089

Re: K133861
Trade/Device Name: FLASH Ostial System OTW-7.0mm x 17mm x 135cm,
FLASH Ostial System OTW-7.0mm x 17mm x 80cm
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: June 4, 2014
Received: June 5, 2014

Dear Mr. Wolenberg,

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" (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 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,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number: K133861

Device Name: FLASH Ostial System OTW

Indication for Use: The FLASH Ostial System OTW is indicated for Percutaneous Transluminal Angioplasty in the peripheral vasculature at aorto-ostial locations, including iliac, renal and carotid arteries. This device is also indicated for post-dilatation of balloon expandable stents in the peripheral vasculature.

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

M A Hillebrenner