



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

May 8, 2015

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

Re: K150946

Trade/Device Name: Flash Ostial System OTW - 6.0mm x 12mm x 80cm,  
Flash Ostial System OTW - 6.0mm x 12mm x 135cm,  
Flash Ostial System OTW - 7.0mm x 12mm x 80cm,  
Flash Ostial System OTW - 7.0mm x 12mm x 135cm

Regulation Number: 21 CFR 870.1250

Regulation Name: Percutaneous Catheter

Regulatory Class: Class II

Product Code: LIT

Dated: April 7, 2015

Received: April 8, 2015

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" (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,

**Kenneth J. Cavanaugh -S**

for

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K150946

Device Name

FLASH Ostial System OTW

Indications for Use (Describe)

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.

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.\***

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  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@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."*

## 510(k) Summary

### FLASH Ostial System OTW – Product Line Extension

#### A. Submitter Information

Submitter's Name: Ostial Corporation  
Address: 1221 Innsbruck Drive  
Sunnyvale, CA 94089  
Telephone: 408-541-1006  
Fax: 408-541-1007  
Email: [jwolenberg@ostialcorp.com](mailto:jwolenberg@ostialcorp.com)  
Contact Person: Jake Wolenberg  
Date of Preparation: April 7, 2015

#### 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 OTW  
510(k) #'s: K133861  
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. All device sizes in the Flash Ostial System OTW product family are designed to be compatible with 6F guiding sheaths. The FLASH Ostial System OTW uses a dual balloon design that features a compliant proximal balloon, which prevents distal migration of the balloon during angioplasty. The second semi-compliant higher-pressure distal 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.



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

The FLASH Ostial System OTW device sizes that are the subject of this Special 510(k) are a line extension of the FLASH Ostial System OTW product line, previously cleared under 510(k) # K133861. The proposed line extension device sizes and previously cleared device sizes are indicated for reference in the table below with a format of Balloon Diameter x Balloon Length x Catheter Length.

Table 8-1: Previously Cleared and Proposed Line Extension Device Sizes

| Flash OTW Line Cleared Device Sizes         | Flash OTW Line Extension Device Sizes                                                      |
|---------------------------------------------|--------------------------------------------------------------------------------------------|
| 7.0mm x 17mm x 80cm<br>7.0mm x 17mm x 135cm | 6.0mm x 12mm x 80cm<br>6.0mm x 12mm x 135cm<br>7.0mm x 12mm x 80cm<br>7.0mm x 12mm x 135cm |

The device sizes included in the line extension all share the exact same catheter design as the currently cleared sizes of the Flash Ostial System OTW. The only differences are the diameter and length of the balloons and the marker band spacing which indicates the length of the balloons. Additionally, the Indications for Use for both versions of the device are exactly the same.

**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 line extension device sizes or product equivalent were 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
- Proximal Balloon Burst Volume
- Angioplasty Balloon Compliance
- Balloon Inflation Time
- Balloon Deflation Time
- Angioplasty Balloon Rated Burst Pressure (in Stent)
- Proximal Balloon Burst Volume (in Stent)
- Angioplasty Balloon Fatigue
- Proximal Balloon Fatigue
- Catheter Bond Strength
- Catheter Tip Pull Strength
- Catheter Torque Strength
- Simulated Use
- Flexibility and Kink Resistance
- Radiopacity
- Angioplasty Balloon Fatigue (in Stent)
- Proximal Balloon Fatigue (in Stent)

All test results demonstrate that the FLASH Ostial System OTW line extension device sizes meet the established product specifications.

**H. Conclusions:**

All test results demonstrated that the FLASH Ostial System OTW line extension device sizes meet all predetermined design verification and validation acceptance criteria necessary to verify safe and consistent performance of the devices for their 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 line extension device sizes to the FLASH Ostial System OTW product family, which was most recently cleared via Premarket Notification 510(k) # K133861 on July 2, 2014.