



Ostial Corporation
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510(k) Summary FLASH Mini Ostial System

A. Submitter Information

Submitter's Name:	Ostial Corporation
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Contact Person:	Jake Wolenberg
Date of Preparation:	May 17, 2013

AUG 06 2013

B. Subject Device

Proprietary Name:	<u>FLASH Mini Ostial System</u>
Common/Usual Name:	PTCA Catheter
Classification Name:	Catheters, Transluminal Coronary Angioplasty, Percutaneous
Product Code:	LOX per 21 C.F.R. 870.5100

C. Predicate Device Name

Proprietary Name:	<u>FLASH Ostial System</u> (a.k.a. Flash-C PTCA Balloon Dilatation Catheter; Flash Ostial Balloon PTCA)
510(k) #'s:	K111284, K113775 and K122178
Common/Usual Name:	PTCA Catheter
Classification Name:	Catheters, Transluminal Coronary Angioplasty, Percutaneous
Product Code:	LOX per 21 C.F.R. 870.5100

D. Device Description:

The FLASH Mini Ostial System is a .014" guidewire-compatible, rapid exchange (RX) angioplasty balloon catheter with proximal anchoring and a working length of 135cm. The FLASH Mini Ostial System 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 Mini Ostial System is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft for the purpose of improving myocardial perfusion. The FLASH Mini Ostial System is also indicated for the post delivery expansion of balloon expandable stents within the coronary vasculature.



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

The FLASH Mini Ostial System that is the subject of this 510(k) is an extension of the FLASH Ostial System product line. The previously cleared device sizes included balloons ranging in diameter from 4.0-6.0mm with working lengths of either 12mm or 17mm. These sizes have a catheter working length of 135cm and are either 6F or 7F compatible. Minor design and process changes have been made to allow for smaller diameter balloons with shorter working length. This submission introduces devices with balloon diameters ranging from 3.0 to 4.5mm and working lengths of 8mm. These new sizes have a catheter length of 135cm and are compatible with 6 French guide catheters.

The only difference between the cleared 6F compatible device sizes and the new device sizes subject to this Special 510(k) are the balloon lengths and diameters. All other aspects of the catheter design and the Indications for Use are the same.

Note: The proprietary name for the previous 510(k)'s filed for this product line was "Flash-C 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 device sizes are intended to be marketed under the proprietary name "FLASH Mini Ostial System".



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G. Performance Data:

Biocompatibility testing has previously been completed on product equivalent to the FLASH Mini Ostial System. 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." 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 Mini Ostial System or product equivalent was evaluated using the following in-vitro 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 Mini Ostial System meets the established product specifications.

H. Conclusions:

All test results demonstrated that the FLASH Mini Ostial System 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 "*balloon dilatation of the stenotic portion of a coronary artery or bypass graft for the purpose of improving myocardial perfusion*" and "*post delivery expansion of balloon expandable stents within the coronary vasculature.*" As such, Ostial Corporation is requesting clearance for the FLASH Mini Ostial System product line extension to the FLASH Ostial System product family, which was most recently cleared via Premarket Notification 510(k) # K122178 on October 11, 2012.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

August 6, 2013

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

Ostial Corporation
Jake Wolenberg
510 Clyde Avenue
Mountain View, CA 94043 US

Re: K131450
Trade/Device Name: FLASH Mini Ostial System
Regulation Number: 21 CFR 870.5100
Regulation Name: Catheters, Transluminal Coronary Angioplasty, Percutaneous
Regulatory Class: Class II
Product Code: LOX
Dated: July 5, 2013
Received: July 8, 2013

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

Enclosure

Ostial Corporation
510(k) Notification: FLASH Mini Ostial System

SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number: K131450
Device Name: FLASH Mini Ostial System

Indication For Use: The FLASH Mini Ostial System is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft for the purpose of improving myocardial perfusion. The FLASH Mini Ostial System is also indicated for the post delivery expansion of balloon expandable stents within the coronary 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)

