



Food and Drug Administration
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February 16, 2016

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

Re: K152485

Trade/Device Name: FLASH Mini Ostial System
(3.0mm x 8mm x 135cm, 3.5mm x 8mm x 135cm,
4.0mm x 8mm x 135cm, and 4.5mm x 8mm x 135cm)
Regulation Number: 21 CFR 870.5100
Regulation Name: Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Regulatory Class: Class II
Product Code: LOX
Dated: January 25, 2016
Received: January 27, 2016

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)

K152485

Device Name

FLASH Mini Ostial System

Indications for Use (Describe)

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.

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.

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Ostial Corporation
510(k) Notification: FLASH Mini Ostial System
Pressure Relief Syringe
K152485

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510(k) Summary

FLASH Mini Ostial System

1.0cc Accessory Syringe Component Modification to Include a Pressure Relief Feature

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
Contact Person: Jake Wolenberg
Date of Preparation: August 20, 2015

B. Subject Device

Proprietary Name: FLASH Mini Ostial System
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: FLASH Mini Ostial System
510(k) #'s: K131450
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 0.014" guidewire-compatible, rapid exchange (RX) coronary angioplasty balloon catheter with a working length of 135cm. The FLASH Mini Ostial System 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 balloon allows for luminal dilatation of *de novo* lesions and post deployment stent expansion.

The FLASH Mini Ostial System is packaged with two accessory syringes. A standard 10cc syringe intended for use in deflation of the Proximal Balloon and a 1.0cc syringe with a pressure relief feature intended for use in inflation of the Proximal Balloon. The pressure relief feature is intended to improve patient safety by limiting the maximum achievable pressure in the Proximal Balloon if the user attempts to inflate the Proximal Balloon when incorrectly positioned.

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.

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

There are no changes being made to the balloon catheters or the 10cc accessory portions of the FLASH Mini Ostial System. The only change being proposed in this traditional 510(k) is the incorporation of a pressure relief feature for the 1.0cc accessory syringe component intended to be used to inflate the Proximal Balloon.

The pressure relief feature is achieved by creating a small hole in barrel of the 1.0cc syringe. A piece of compliant silicone tubing is secured over the hole. When the pressure in the syringe exceeds a certain level, fluid leaves through the hole and starts to fill the silicone tubing instead of the Proximal Balloon. This limits the maximum pressure achievable in the Proximal Balloon to a level that will not result in significant expansion, even if the user inflates the balloons while the device is incorrectly positioned.

The incorporation of the pressure relief feature to the 1.0cc accessory syringe component does not affect the device's operating principles or mechanism of action (the balloon catheters remain exactly the same and 1.0cc syringe still functions via manual depression of a plunger). In addition, the same materials and processes used to make the currently cleared FLASH Mini Ostial System are used for the 1.0cc accessory syringe component with the pressure relief feature.

The addition of the pressure relief feature does not affect the intended use of the FLASH Mini Ostial System. The Indications for Use remain exactly the same.

The Pressure Relief Syringe is intended to be packaged with all of the device sizes in the FLASH Mini Ostial System product family currently cleared under 510(k) # K131450. A summary of the currently cleared device sizes can be found in the table below.

Table 8 - 1: Device Sizes Cleared via 510(k) #K131450

510(k) Number	Clearance Date	Device Sizes ¹
K131450	August 6, 2013	3.0mm x 8mm x 135cm 3.5mm x 8mm x 135cm 4.0mm x 8mm x 135cm 4.5mm x 8mm x 135cm

Note 1 - Balloon Diameter x Balloon Length x Catheter Length

G. Previously Presented Performance Data:

As there are no changes being made to the FLASH Mini Ostial System balloon catheters, the previously collected performance data presented in special 510(k) K131450 remains valid. The previously presented data has been summarized for reference below. Note that as the data remains unchanged, it is not presented in the main body of this traditional 510(k). Please refer to Special 510(k) K131450 for this data.

Balloon Catheter Performances Data Previously Presented in 510(k) K131450

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
- 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)

H. New Performance Data:

As the purpose of this Traditional 510(k) is to request clearance for the incorporation of a pressure relief feature for the 1.0cc accessory syringe component included with the FLASH Mini Ostial System product line, the performance data presented herein focuses on the functionality of the pressure relief feature and ensuring that the syringe remains compatible with the balloon catheter.

The 1.0cc accessory syringe components with the pressure relief feature, herein referred to as the Pressure Relief Syringe, were evaluated for the following in-vitro and performance bench testing to confirm the performance characteristics as compared to the product performance requirements:

Pressure Relief Syringe Performance Requirements

- Minimum Expansion Pressure
- Maximum Expansion Pressure
- Freedom from Leakage

Balloon Catheter Compatibility Requirements

- Proximal Balloon Inflation Time
- Simulated Use and Proximal Balloon Inflation Port Compatibility

All test results demonstrate that the pressure relief feature does not impact the use of the device under normal operating conditions. Additionally, the test result demonstrates that the Pressure Relief Syringe consistently limits the maximum pressure that can be achieved in the Proximal Balloon.

I. Conclusions:

All test results demonstrated that the accessory Pressure Relief Syringe component of the FLASH Mini Ostial System meets all predetermined design verification and validation acceptance criteria necessary to verify safe and consistent performance of the Pressure Relief Syringe. As such, Ostial Corporation is requesting clearance for the addition of the pressure relief feature to the 1.0cc inflation syringe included with all FLASH Mini Ostial System device sizes, which were most recently cleared via Premarket Notification 510(k) #K131450 on August 6, 2013.