K122379

SECTION 5: 510(k) SUMMARY

SEP 5 2012

A. Submitter Information

Submitter's Name:	Ostial Corporation
Address:	510 Clyde Avenue Mountain View, CA 94043
Telephone:	650-903-9100
Fax:	650-903-9119
Email:	kvonhoffmann@ostialcorp.com
Contact Person:	Kaitlin von Hoffmann
Date of Preparation:	August 3, 2012

B. Subject Device

Trade Name:	Flash PTA Balloon Dilatation Catheter
Common/Usual Name:	Balloon Catheter
Classification Name:	Catheters, Angioplasty, Peripheral, Transluminal
Product Code:	LIT per 21 C.F.R. 870.1250

C. Device Description:

The Flash PTA Balloon Dilatation Catheter is designed for the dilation of stenotic ostial lesions in the peripheral vasculature. The Flash PTA Balloon Dilatation Catheter is a 0.014" guidewire-compatible, rapid exchange (RX) angioplasty balloon catheter with proximal anchoring. The Flash PTA Balloon Dilatation Catheter uses a dual balloon design, which prevents distal migration of the balloon during angioplasty. The distal semi-compliant higher-pressure balloon allows for luminal dilatation of *de novo* lesions and post deployment stent expansion.

D. Intended Use:

The Flash PTA Balloon Dilatation Catheter 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.

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

The Flash PTA Balloon Dilatation Catheter that is the subject of this 510(k) is an extension of a product line of the same name, which was cleared via 510(k) #K121175 on June 29, 2012. This submission includes devices with balloon diameters ranging from 4.0 to 7.0mm and balloon lengths of 14 and 19mm. The new sizes feature a working catheter length of 135cm, and are compatible with either 6 or 7 French guide catheters. With the exception of the 7mm model, all of these models have previously been cleared by the FDA for a subset of the proposed indication via 510(k) #K120738 on March 29, 2012.

F. Performance Data:

Biocompatibility testing has previously been completed on the Flash PTA Balloon Dilatation Catheter. 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
- Materials Mediated Rabbit Pyrogen
- ISO Guinea Pig Maximization Sensitization

- Complement Activation C3a and SC5b-9 Assay
- Thromboresistance Evaluation
- Pyrogen (LAL) Chromogenic
- ISO Acute Systemic Injection Test
- ISO Intracutaneous Reactivity Test

The Flash PTA Balloon Dilatation Catheter was evaluated using the following in-vitro performance bench testing to confirm the performance characteristics as compared to the predicate device:

- Balloon Crossing Profile
- Catheter Shaft 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 Fatigue (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)

All test results demonstrate that the device materials, the manufacturing process, and the design for the Flash PTA Balloon Dilatation Catheter met the established specifications necessary for consistent performance according to its intended use.

G. Conclusions:

The Flash PTA Balloon Dilatation Catheter 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.

The purpose of this 510(k) is to request clearance for an extension of the Flash PTA Balloon Dilatation Catheter product line cleared via 510(k) #K121175 on June 29, 2012. The Flash PTA Balloon Dilatation Catheter met all predetermined acceptance criteria of design verification and validation as specified by applicable standards, test protocols, and/or customer inputs.

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

SEP 5 2012

Ostial Corporation
c/o Kaitlin von Hoffmann
510 Clyde Avenue
Mountain View, CA 94043

Re: K122379
Trade/Device Name: Flash PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT, DQY
Dated: August 03, 2012
Received: August 06, 2012

Dear Ms. 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) 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

SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number: K122379

Device Name: Flash PTA Balloon Dilatation Catheter

Indication for Use: The Flash PTA Balloon Catheter 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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K122379