

K120805

APR 13 2012

510(k) Summary

PROTEUS™ PTA Catheter with Embolic Capture Feature

Introduction:

This document contains the 510(k) summary for the modified PROTEUS™ PTA Catheter with Embolic Capture Feature. The content of this summary is based on the requirements of 21 CFR Section 807.92(c).

Applicant Name and Address:

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Summary Preparation Date: March 14, 2012

Device Name and Classification:

Trade Name: PROTEUS™ PTA Balloon Catheter with
Embolic Capture Feature
Common Name: Percutaneous Transluminal Angioplasty
Balloon Catheter
Classification Name: Catheter, Percutaneous
Classification: Class II, 21 CFR 870.1250
Product Code DQY/LIT

Predicate Devices:

The modified PROTEUS™ Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter with Embolic Capture Feature is claimed to be substantially equivalent to the following legally marketed predicate devices:

- Angioslide PROTEUS™ PTA Balloon Catheter with Embolic Capture Feature (K111750)
- Boston Scientific Sterling® SL Monorail PTA Balloon, Dilation Catheter (K093720)

Performance Standards: There are no mandatory performance standards for this device.

Device Description: (see Figure 1)

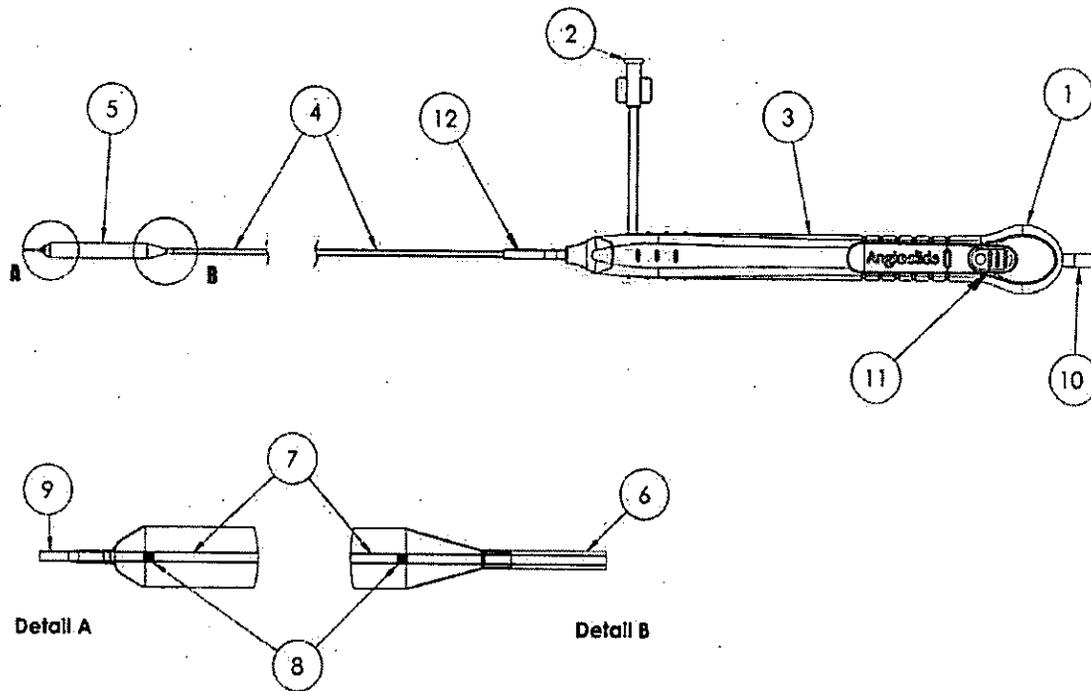


Figure 1

The Angioslide PROTEUS™ Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter with Embolic Capture Feature is an over the wire dual lumen catheter with a foldable balloon (5) located near the distal atraumatic soft tip (9).

One lumen is used for inflation of the balloon and is accessed via the inflation port (2). The other lumen, starting at the guidewire port (10), allows access to the distal tip for guidewire insertion (max. 0.035"). The balloon has two radiopaque markers (8) for positioning the balloon relative to stenosis. The radiopaque markers indicate the dilating section of the balloon and help in balloon placement. The balloon is designed to provide an inflatable segment of known diameter and length at specified pressure.

The Angioslide PROTEUS™ Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter with Embolic Capture Feature is an over the wire dual lumen catheter with a foldable balloon (5) located near the distal atraumatic soft tip (9).

One lumen is used for inflation of the balloon and is accessed via the inflation port (2). The other lumen, starting at the guidewire port (10), allows access to the distal tip for guidewire insertion. The balloon has two radiopaque markers (8) for positioning the balloon relative to stenosis. The radiopaque markers indicate the dilating section of the balloon and help in balloon placement.

The balloon is designed to provide an inflatable segment of known diameter and length at specified pressure.

Indications for Use:

The PROTEUS™ Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter with Embolic Capture Feature is indicated for peripheral transluminal angioplasty and for capture and containment of embolic material during angioplasty, for the femoral, iliac, ilio-femoral, popliteal, tibial, peroneal, and profunda arteries.

The PROTEUS™ PTA Balloon Catheter with Embolic Capture Feature is not intended for use in the renal, cerebral, coronary or carotid vasculature.

Comparison of Modified Indications for Use:

The Indications for Use for the predicate PROTEUS™ Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter with Embolic Capture Feature (K111750) are identical to the modified PROTEUS™ Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter with Embolic Capture Feature, but includes the addition of the 3x100mm balloon size.

Comparison of Technological Characteristics:

The PROTEUS™ Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter is an over the wire co-axial dual lumen catheter with a foldable balloon located near the distal atraumatic soft tip. The catheter is compatible with a 0.014” guidewire in the 3x100mm size only, and a 0.035” guidewire for all other sizes, which are currently cleared.

The balloon technological characteristics of the modified PROTEUS™ PTA Balloon Catheter are substantially equivalent to those of the PROTEUS™ PTA Balloon Catheter and the Sterling® SL Monorail PTA Balloon Dilation Catheter. In both devices lesion dilation is achieved by means of an inflatable balloon.

The modified PROTEUS™ PTA Balloon Catheter overall length, catheter sheath sizing, balloon diameter, balloon length, balloon nominal pressure, balloon rated burst pressure and end hole diameter are the same or similar to the PROTEUS™ PTA Balloon Catheter and the Sterling® SL Monorail PTA Balloon Dilation Catheter.

The embolic capture technological characteristics of the modified PROTEUS™ PTA Balloon Catheter are identical to those of the PROTEUS™ PTA Balloon Catheter. In both devices the containment and removal of embolic material is achieved by proximal vessel occlusion, by means of an inflatable balloon, and subsequent aspiration of embolic material.

Summary of Non-Clinical Testing:

In vitro bench testing of the Angioslide PROTEUS™ PTA Balloon Catheter was conducted in accordance with Angioslide’s Risk Analysis and all applicable FDA Guidance documents and ISO standards, including:

- ISO 10555-1 – Sterile, Single Use Intravascular Catheters- Part 1: General Requirements
- ISO 10555-4 – Sterile, Single Use Intravascular Catheters- Part 4: Balloon Dilatation Catheters

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FDA Guidance – Non-Clinical Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems, January 13, 2005

FDA Guidance – Coronary and Carotid Embolic Protection Devices - Premarket Notification [510(k)] Submissions, February 15, 2008

All bench testing, unless otherwise specified, was conducted using finished devices which were sterilized by the final validated sterilization process.

Design Verification and Validation:

Sample sizes used for the testing were based on required confidence/reliability levels as per FDA Guidance “Non-Clinical Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems “ and the results of the risk analysis (DFMEA) performed for the PROTEUS™ PTA catheter. The number of units utilized for each test depends on whether the data to be collected was variable data or attribute data, therefore the number of units tested varies from test to test. However, in all cases, the number utilized for testing met the required number of units based on the risk analysis, and the required confidence/reliability levels.

The results of verification and validation testing demonstrated that the modified PROTEUS™ PTA Balloon Catheter with Embolic Capture Feature design met all specifications, and is adequate for its intended use. Additionally, the test results demonstrated substantial equivalence of the modified PROTEUS™ PTA Balloon Catheter with Embolic Capture Feature to its predicate devices.

Verification and validation testing of the modified PROTEUS™ PTA Balloon Catheter with Embolic Capture Feature included catheter and balloon dimensional evaluation, minimum balloon burst strength (RBP), balloon compliance, balloon inflation and deflation time, balloon fatigue, tensile strength, simulated use, and capture efficiency testing.

Test	Accept/Reject Criteria	Results
Visual inspection – external surface	External surface of catheter effective length, including the distal end, is free from extraneous matter and surface defects (<0.2mm ² TAPPI). 90% Confidence, 90% Reliability	PASS
Visual inspection – distal tip	Distal tip is smooth, rounded, tapered, or similarly finished. 90% Confidence, 90% Reliability	PASS
Distal Bond Outer Diameter	In Tolerance 90% Confidence, 90% Reliability	PASS
Distal Balloon Cone to Distal Tip	In Tolerance 90% Confidence, 90% Reliability	PASS
Distal Tip to Proximal Outer Tube Tip Length	In Tolerance 90% Confidence, 90% Reliability	PASS
Soft Tip Length	In Tolerance 90% Confidence, 90% Reliability	PASS
Wrapped Balloon Outer Diameter	In Tolerance 90% Confidence, 90% Reliability	PASS
Guide Wire Lumen Inner Diameter	In Tolerance 90% Confidence, 90% Reliability	PASS
Proximal Bond Outer Diameter	In Tolerance 90% Confidence, 90% Reliability	PASS

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Test	Accept/Reject Criteria	Results
Marker Band Spacing	In Tolerance 90% Confidence, 90% Reliability	PASS
Balloon Working Length	In Tolerance 90% Confidence, 90% Reliability	PASS
Balloon Outer Diameter	In Tolerance 90% Confidence, 90% Reliability	PASS
Catheter Overall Effective Length	In Tolerance 90% Confidence, 90% Reliability	PASS
Catheter Overall Length	In Tolerance 90% Confidence, 90% Reliability	PASS
Minimum Balloon Burst Pressure (RBP)	RBP \geq 14atm 95% Confidence, 99.9% Reliability	PASS
Balloon Fatigue (Repeated Inflation/Deflations)	Inflation/Deflation Cycles \geq 10 at 14atm (for 3x100) No leakage, rupture, and/or herniation Up to max 40 cycles 95% Confidence, 90% Reliability	PASS
Tensile Strength- Distal Balloon to Inner Tube (Peel)	\geq 5N 90% Confidence, 95% Reliability	PASS
Tensile Strength- Distal Balloon to Inner Tube (Shear)	\geq 5N 90% Confidence, 95% Reliability	PASS
Tensile Strength- Proximal Balloon to Outer Tube	\geq 10N 90% Confidence, 95% Reliability	PASS
Tensile Strength- Cylinder to T-Connector	\geq 15N 90% Confidence, 90% Reliability	PASS
Tensile Strength- Inflation Tube to T-Connector	\geq 15N 90% Confidence, 90% Reliability	PASS
Tensile Strength- Outer Tube to T-Connector	\geq 15N 90% Confidence, 90% Reliability	PASS
Tensile Strength- Inner Shaft to Pulling Rod	\geq 10N 90% Confidence, 95% Reliability	PASS
Tensile Strength- Pulling Rod to Proximal Luer	\geq 15N 90% Confidence, 90% Reliability	PASS
Tensile Strength- Pulling Rod to Knob Base	\geq 15N 90% Confidence, 90% Reliability	PASS
Tensile Strength- Cylinder to O-ring Cap	\geq 15N 90% Confidence, 90% Reliability	PASS
Liquid Leakage	No leakage 90% Confidence, 90% Reliability	PASS
Balloon Inflation/Deflation Testing	Inflation Time: \leq 14.0s Deflation Time: \leq 30.6s 90% Confidence, 90% Reliability	PASS
Balloon Compliance	Compliance: \leq 13% Nominal Pressure: 8atm RBP: 14atm 90% Confidence, 90% Reliability	PASS
Flow Characteristics- Straight Configuration	Distal flow observed in uninflated and deflated state, occlusion of distal flow in inflated state 90% Confidence, 90% Reliability	PASS
Flow Characteristics- Extreme Angle Configuration	Distal flow observed in uninflated and deflated state, occlusion of distal flow in inflated state 90% Confidence, 90% Reliability	PASS

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Test	Accept/Reject Criteria	Results
Stroke Length	Minimum Stroke Length: ≥ 70% of the associated Balloon Working Length Maximum Stroke Length: Balloon can be deflated after reaching stroke limit. 90% Confidence / 90% Reliability	PASS
Simulated Use in Tortuous Anatomy Model – guide wire compatibility	Catheter can be mounted over a 0.014” guide wire 90% Confidence, 90% Reliability	PASS
Simulated Use in Tortuous Anatomy Model – Introducer Sheath Compatibility	Completely folded balloon passes through identified Introducer Sheath at the end of procedure. 90% Confidence, 90% Reliability	PASS
Simulated Use in Tortuous Anatomy Model – Kink Resistance	No permanent deformations (kinks) are present once removed from the tortuous anatomy model. 90% Confidence, 90% Reliability	PASS
Simulated Use in Tortuous Anatomy Model – Max Advancement Force	N/A – Characterization only	N/A
Simulated Use in Tortuous Anatomy Model – Max Collapse Force	N/A – Characterization only	N/A
Simulated Use in Tortuous Anatomy Model – Max Anatomy Retraction Force	N/A – Characterization only	N/A
Simulated Use in Tortuous Anatomy Model – Max Removal Retraction Force	N/A – Characterization only	N/A
Capture Efficiency Comparison	N/A – Characterization only	N/A

Comparative Capture Efficiency Testing:

To ensure comparability of results, the testing approach was identical to that used to gather baseline data submitted in the original 510(K) for the eXtra™ device family (K090364). The CE testing for the modified PROTEUS™ PTA Balloon Catheter was identical to that of its predicate and is comparable to events that could happen *in vivo*.

A review of the data in detail revealed no significant anomalies in the raw or analyzed data; and trends in performance based on differences in device size were as expected.

Biocompatibility Testing:

Based on Risk Analysis, no additional biocompatibility testing was required for this modification.

Sterilization:

The PROTEUS™ PTA Balloon Catheter is packaged and sterilized using substantially equivalent materials, methods, and sterilization parameters used for most commercially available PTA balloon catheter products. The PROTEUS™ PTA Balloon Catheter is sterilized by ethylene oxide (EtO) sterilization providing a Sterility Assurance Level (SAL) of 1×10^{-6} . EtO sterilization validation was completed in accordance with ISO 11135-1:2007 “Medical devices – Validation and routine control of ethylene oxide sterilization”. Testing of EtO residuals was performed in

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accordance with ISO 10993-7:2008 “Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals.” Results of the sterilization validation were found to meet all acceptance criteria, confirmed a SAL of 1×10^{-6} , and EtO/ECh residuals were found to be within the ISO 10993-7 standard specification.

Packaging:

There have been no changes to the packaging materials or assembly for the modified PROTEUS™ PTA Balloon Catheter from its predicate device, K111750; therefore, no packaging validation was performed.

Shelf Life:

The shelf-life of the modified PROTEUS™ PTA Balloon Catheter is identical to the currently validated three (3) year shelf life for its predicate device, PROTEUS™ PTA Balloon Catheter. Therefore, no shelf-life validation or accelerated aging tested were performed.

Substantial Equivalence Conclusion:

The modified Angioslide PROTEUS™ PTA Balloon Catheter is substantially equivalent with respect to the indications for use, technological characteristics and performance characteristics to the following legally marketed predicate devices:

- PROTEUS™ PTA Balloon Catheter, Angioslide – K111750
- Sterling® SL Monorail PTA Balloon Catheter, Boston Scientific – K093720



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

Angioslide, LTD.
c/o Clay Anselmo
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APR 13 2012

Re: K120805

Trade/Device Name: PROTEUS™ PTA Balloon Catheter with Embolic Capture Feature
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT, DQY
Dated: March 14, 2012
Received: March 16, 2012

Dear Mr. Anselmo:

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" (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 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,



f 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): K120805

Device Name: PROTEUS™ Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter with Embolic Capture Feature

Indications for Use:

The Angioslide PROTEUS™ Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter with Embolic Capture Feature is indicated for peripheral transluminal angioplasty and for capture and containment of embolic material during angioplasty, for the femoral, iliac, ilio-femoral, popliteal, tibial, peroneal, and profunda arteries.

The Angioslide PROTEUS™ PTA Balloon Catheter with Embolic Capture Feature is not intended for use in the renal, cerebral, coronary or carotid vasculature.

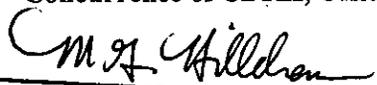
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 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

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