December 15, 2017

Angioslide, Ltd.
% Ilya Burovoy
Principal Consultant
Ilya Burovoy- Regulatory and Quality Consulting
21 Montefiore St. #17
Kiryat Ono, 5522635 Israel

Re: K172494
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
Dated: November 19, 2017
Received: November 22, 2017

Dear Ilya Burovoy:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172494

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

Indications for Use *(Describe)*
The Angioslide PROTEUS™ Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter with Embolic Capture Feature is indicated for peripheral transluminal angioplasty and for capture and removal of embolic material (e.g. debris, thrombus) 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.

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.

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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: August 2, 2017

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	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 Ltd. - Special 510(k) PROTEUS™ PTA Catheter with Embolic Capture Feature
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- Angioslide PROTEUS™ PTA Balloon Catheter with Embolic Capture Feature (K133043)

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

Device Description: (see Figure 1)

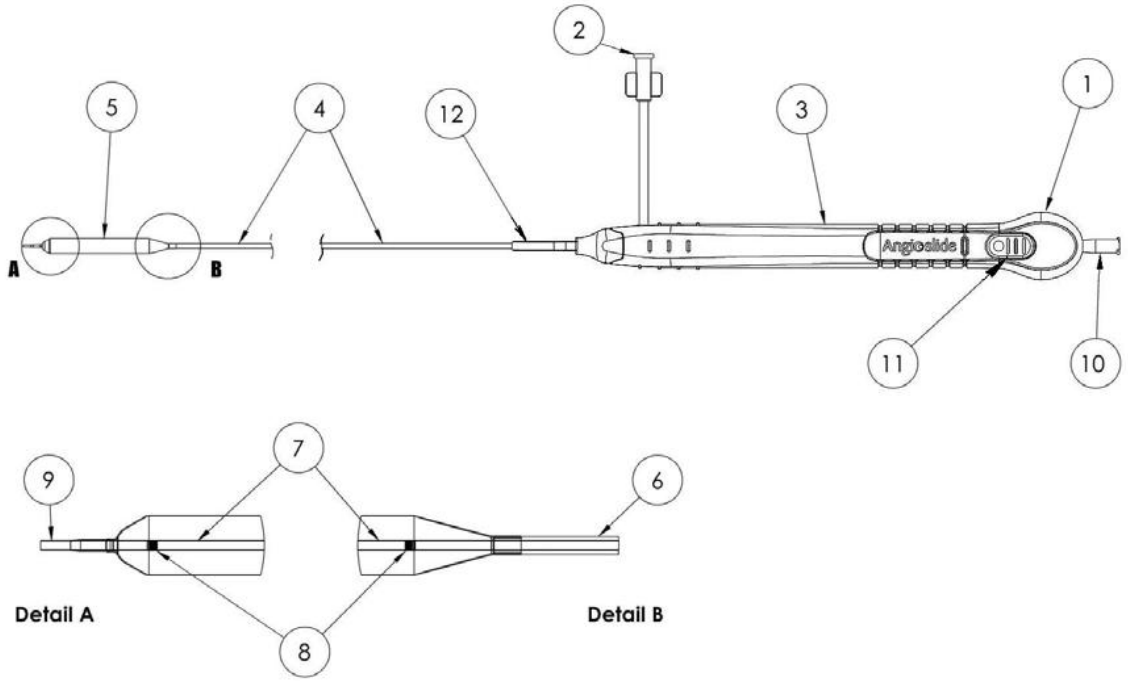

Figure 1

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 shaft (4) comprises the outer shaft (6) and the inner shaft (7). The distal end of the balloon (A) is connected to the inner shaft and the proximal end of the balloon (B) is connected to the outer shaft. The inner shaft is connected to the proximal hub (10) which is connected to the pulling knob (1) and the outer shaft is connected to the handle grip (3). The pulling knob lock (11) locks the handle grip and the pulling knob together. The distal end of the balloon is folded inwards towards the proximal end of the balloon, by pressing on pulling knob lock (11) and pulling the pulling knob away from the handle (1). The inward-folding of the balloon forms a cavity and allows for collection and removal of embolic material.

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The balloon size and diameter are printed on the strain relief (12). Refer also to the package label for information about catheter length, balloon nominal and rated burst pressure, balloon size, balloon compliance, guidewire compatibility and sheath compatibility.

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 removal of embolic material (e.g. debris, thrombus) 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.

Comparison of Indications for Use:

The Indications for Use for the predicate PROTEUS™ Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter with Embolic Capture Feature (K133043) are identical to the modified PROTEUS™ Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter with Embolic Capture Feature.

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 predicate PROTEUS™ PTA Balloon. In both devices lesion dilation is achieved by means of an inflatable balloon.

The modified PROTEUS™ PTA Balloon Catheter overall length, 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.

The modified PROTEUS™ PTA Balloon Catheter differs from the predicate device in that the introducer sheath sizing for 6x60mm, 6x80mm and 6x100mm balloons is 6Fr as compared to 7Fr for the predicate PROTEUS™ PTA Balloon Catheter. The change of the PROTEUS™ device 6x60, 6x80 and 6x100mm balloons compatibility from 7Fr to 6Fr introducer sheath includes minor changes to the balloons’ distal end geometry to facilitate passage of the folded balloon through the introducer sheath of a smaller diameter.

The modified PROTEUS™ PTA Balloon Catheter differs from the predicate device in cancelling the handle pulling knob end position lock feature for the 5x60, 5x80, 5x100, 6x60, 6x80 and 6x100mm balloon sizes. This modification is aimed to improve user comfort by improving usability of the pulling knob feature.

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The modified PROTEUS™ PTA Balloon Catheter differs from the predicate device in the handle internal sealing design for the 5x60, 5x80, 5x100, 6x60, 6x80 and 6x100mm balloon sizes.

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 capture 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

FDA Guidance – Non-Clinical Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems, April 18, 2010

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

FDA Guidance - Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters, September 8, 2010

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 and simulated use. No additional capture efficiency testing was required for the modified PROTEUS™ PTA Balloon Catheter as previous testing continues to support the capture efficiency performance.

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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
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
Marker Band Spacing	In Tolerance 90% Confidence, 90% Reliability	PASS
Balloon Working Length	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
Distal Tip Inner Diameter	In Tolerance 90% Confidence, 90% Reliability	PASS
Minimum Balloon Burst Pressure (RBP)	RBP ≥ 12atm 95% Confidence, 99.9% Reliability	PASS
Balloon Fatigue (Repeated Inflation/Deflations)	Inflation/Deflation Cycles ≥ 10 at 12atm No leakage, rupture, and/or herniation 95% Confidence, 90% Reliability Up to max 20 cycles	PASS
Tensile Strength- Distal Balloon to Inner Tube (Peel)	≥ 10N 90% Confidence, 95% Reliability	PASS
Tensile Strength- Distal Balloon to Inner Tube (Shear)	≥ 10N 90% Confidence, 95% Reliability	PASS
Tensile Strength- Proximal Balloon to Outer Tube	≥ 10N 90% Confidence, 90% Reliability	PASS
Tensile Strength- Cylinder to T-Connector	≥ 15N 90% Confidence, 90% Reliability	PASS
Tensile Strength- Inflation Tube to T-Connector	≥ 15N 90% Confidence, 90% Reliability	PASS
Tensile Strength- Outer Tube to T-Connector	≥ 10N 90% Confidence, 90% Reliability	PASS
Tensile Strength- Inner Shaft to Pulling Rod	≥ 10N 90% Confidence, 95% Reliability	PASS
Tensile Strength- Pulling Rod to Proximal Luer	≥ 15N 90 % Confidence, 90% Reliability	PASS
Tensile Strength- Pulling Rod to Knob Base	≥15N 90% Confidence, 90% Reliability	PASS
Tensile Strength- Cylinder to O-ring Cap	≥ 15N 90% Confidence, 90% Reliability	PASS

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Test	Accept/Reject Criteria	Results
Liquid Leakage	No leakage 90% Confidence, 90% Reliability	PASS
Balloon Inflation/Deflation Testing	Inflation Time: ≤ 14.0s Deflation Time: ≤ 30.6s No leakage on Inflation 90% Confidence, 90% Reliability	PASS
Balloon Compliance	Compliance: ≤ 13% Nominal Pressure: 8atm RBP: 12atm 90% Confidence, 90% Reliability	PASS
Balloon OD at Nominal Pressure	Balloon Outer Diameter within Tolerance @Nominal Pressure 8atm 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
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 0.035” 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

Comparative Capture Efficiency Testing:

The modified PROTEUS™ PTA Balloon Catheter includes modification of the 6x60, 6x80mm and 6x100mm balloon sizes which do not represent the worst case from the Capture Efficiency prospective therefore the Capture Efficiency test data submitted with the predicate PROTEUS™ PTA Balloon Catheter K133043 remains representative to provide sufficient supporting evidence

for substantial equivalence of the entire modified device family and no additional Capture Efficiency testing was required for this modification.

Biocompatibility Testing:

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

Sterilization:

There have been no changes to the sterilization method or parameters of the EtO sterilization process and packaging materials or methods of the device since the clearance of the predicate device K133043; therefore, no sterilization validation was performed.

Packaging:

There have been no changes to the packaging materials or assembly for the modified PROTEUS™ PTA Balloon Catheter from its predicate device, K133043; therefore, no packaging validation was performed.

Shelf Life:

Apart from the 6x60, 6x80 and 6x100mm balloon sizes 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.

The modified Angioslide PROTEUS™ 6x60, 6x80 and 6x100mm balloon sizes have been validated for one (1) year shelf life to support the modification in geometry of the balloons.

The shelf life testing included:

- visual inspection,
- dimensional inspection,
- burst pressure testing,
- fatigue testing,
- inflation/deflation testing,
- balloon compliance testing,
- bond tensile strength testing,
- simulated use testing,
- flow characterization.

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 Ltd. – K133043