DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

December 2, 2016

Philips Volcano
Mary Stanners
Regulatory Affairs Specialist
3721 Valley Centre Drive, Suite 500
San Diego, CA 92130

Re: K162418
Trade/Device Name: Pioneer Plus Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU, ITX
Dated: November 02, 2016
Received: November 04, 2016

Dear Ms. Stanners:

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,

Brian D. Pullin -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162418

Device Name
Pioneer Plus Catheter

Indications for Use *(Describe)*
The Pioneer Plus catheter is intended to facilitate placement and positioning of catheters within the peripheral vasculature. The Pioneer Plus catheter also provides an intraluminal cross-sectional ultrasound image of the area of interest to facilitate placement of guidewires beyond stenotic lesions (e.g., sub-total, total or chronic total occlusions) prior to additional intervention (i.e. PTA, stent, etc.). The Pioneer Plus catheter is not indicated for use in the coronary or cerebral 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) SUMMARY

SPONSOR: Philips Volcano
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DATE OF SUBMISSION: November 2, 2016

DEVICE:

Trade Name: Pioneer Plus Catheter

Common Name: Diagnostic Ultrasound Transducer and Ultrasound Transducer

Classification and Product Codes:

CFR Number	Class	Product Code
21 CFR 870.1250 Percutaneous Catheter	II	PDU
21 CFR 892.1570 Diagnostic Ultrasound Transducer	II	ITX

PREDICATE DEVICE:

510(k) Number: K101777

Trade Name: Pioneer Plus Catheter

Common Name: Diagnostic Ultrasound Transducer and Ultrasound Transducer

Classification and Product Codes:

CFR Number	Class	Product Code
21 CFR 870.1250 Percutaneous Catheter	II	PDU
21 CFR 892.1570 Diagnostic Ultrasound Transducer	II	ITX

DEVICE DESCRIPTION:

The Pioneer Plus catheter is intended to facilitate placement and positioning of catheters within the peripheral vasculature. The Pioneer Plus catheter also provides an intraluminal cross-sectional ultrasound image of the area of interest to facilitate placement of guidewires beyond stenotic lesions (e.g., sub-total, total or chronic total occlusions) prior to additional intervention (i.e. PTA, stent, etc.). The Pioneer Plus catheter is not indicated for use in the coronary or cerebral vasculature.

The Pioneer Plus catheter is a dual lumen catheter that is inserted through a commercially available 6F introducer sheath and placed percutaneously into a peripheral vessel. The Pioneer Plus catheter tracks to its intended site in the vasculature over a standard, commercially available 0.014" (0.36 mm) tracking guidewire. The Pioneer Plus catheter utilizes an extendable, hollow Nitinol needle - minimum internal needle diameter: 0.016" (0.43 mm); it is compatible with floppy 0.014" (0.36 mm) over the wire (OTW) guidewires to facilitate the redirection and placement of the guidewire into peripheral vessels. The needle orientation placement is achieved through the use of an intravascular ultrasound (IVUS) transducer mounted at the distal end of the Pioneer Plus catheter. The Pioneer Plus catheter operator navigates the peripheral vasculature under fluoroscopic guidance and uses IVUS imaging to direct the needle to achieve optimal placement. The operator uses the Needle Deployment Ring incorporated into the handle of the Pioneer Plus catheter to extend the needle from the catheter. The needle can be extended up to 7mm in length, or to a pre-determined distance using the Stop Ring. A 0.014" (0.36 mm) OTW guidewire (needle guidewire) can then be advanced through the needle and used to facilitate the placement of subsequent catheters once the Pioneer Plus device is withdrawn.

INDICATIONS FOR USE:

The indications for Use remain the same and are as follows:

The Pioneer Plus catheter is intended to facilitate placement and positioning of catheters within the peripheral vasculature. The Pioneer Plus catheter also provides an intraluminal cross-sectional ultrasound image of the area of interest to facilitate placement of guidewires beyond stenotic lesions (e.g., sub-total, total or chronic total occlusions) prior to additional intervention (i.e. PTA, stent, etc.). The Pioneer Plus catheter is not indicated for use in the coronary or cerebral vasculature.

COMPARISON OF TECHNOLOGICAL CHARACTERISICS:

The modification made to the Pioneer Plus Catheter is a double wrap of Vestamid sheath material to the area located at the bonded joint of the braided stainless steel outer shaft and the Vestamid distal sleeve to improve braid containment. The Vestamid sheath material is already used on the Pioneer Plus Catheter,

there is just an additional wrap of that same material that did not change the Outer Dimension (OD). There was also tightening of a specification for the braided wire and an inspection method. The modifications do not affect the intended use of the device or technologies and it does not alter the fundamental scientific technologies. The proposed design change does not change the fundamental operating principles of the device. The indications for use are identical to those of the currently marketed device. These changes have no impact to the Pioneer Plus Catheter sterilization, materials, or packaging. The modified catheter is substantially equivalently to currently marketed device.

PERFORMANCE DATA:

Non-clinical device testing was conducted to confirm the performance of the modified device. Bench testing was conducted against known standards or product specification and evaluated Visual Inspection, Outer Diameter (OD) Measurement, Braid Durability, Bend Radius (Kink) and Tensile Testing. All testing met the acceptance criterial with 95/95 confidence/reliability.
The successful completion of performance testing concluded that the modified Pioneer Plus Catheter is substantially equivalent to the current Pioneer Plus Catheter.

The design change did not introduce new material and does not impact sterility or packaging.All packaging materials and processes remain the same. The sterile barrier system remains the same. The modified Pioneer Plus Catheter is packaged in the same configuration as the current Pioneer Plus.

For this Pioneer Plus Catheter modification, the following standards as described in this submission's FDA 3654 Standards forms (**Attachment F**) were followed:

BS EN ISO 13485:2012	Medical Devices Quality Management System Requirements for Regulatory Purposes
ISO 14971:2012	Medical Devices - Application of Risk Management to Medical Devices
10993-1	Biological Evaluation of Medical Devices – Part 1: Evaluating and Testing within a Risk Management Process
10993-4	Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood
10993-5	Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity

The following tests were completed; visual inspection, outer diameter (OD) measurement, braid durability, bend radius and tensile testing and the modified Pioneer Plus Double Layer Joint design change met all acceptance criteria.