



August 4, 2016

Bard Peripheral Vascular, Inc.
Ms. Melanie Hadlock
Regulatory Affairs Specialist
1625 West 3rd Street
Tempe, AZ 85281

Re: K161986

Trade/Device Name: Sidekick and Usher Support Catheters
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: July 18, 2016
Received: July 19, 2016

Dear Ms. Hadlock:

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,



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)

K161986

Device Name

SIDEKICK® and USHER® Support Catheters

Indications for Use (Describe)

The SIDEKICK® and USHER® Support Catheters are single lumen catheters intended to create a pathway for other devices in the peripheral 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
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“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”

Special 510(k): Device Modification
SIDEKICK[®] and USHER[®] Support Catheters

510(k) Summary

[As required by 21 CFR 807.92(c)]

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (l)(3)(A) of the Food, Drug and Cosmetic Act, a summary of the information upon which substantial equivalence determination is based is as follows:

1. Submitter Information:

Applicant: Bard Peripheral Vascular, Inc.
1625 West 3rd Street
Tempe, Arizona 85281

Phone: 480.350.6083

Fax: 480.449.2546

Contact: Melanie Hadlock, Regulatory Affairs Specialist

Date: July 18, 2016

2. Subject Device:

Device Trade Name:	SIDEKICK [®] and USHER [®] Support Catheters
Common Name:	Percutaneous Catheter
Device Classification	Class II
Classification Name:	Percutaneous Catheter
Classification Product Code:	DQY
Regulation Number:	21 CFR 870.1250
Review Panel:	Cardiovascular

3. Predicate Device:

SIDEKICK[®] and USHER[®] Support Catheters (K131493)

Reference devices: ULTRAVERSE[®] 035 PTA Dilatation Catheter (K142261, cleared September 24, 2014); CROSSER[®] CTO Recanalization Catheter (K161208, cleared May 24, 2016).

Special 510(k): Device Modification
SIDEKICK[®] and USHER[®] Support Catheters

4. Summary of Change:

The GEOALIGN[®] Marking System has been added to the device. The GEOALIGN[®] Marking System is a non-radiopaque ruler on the catheter shaft measured from the distal tip.

5. Device Description:

The SIDEKICK[®] and USHER[®] Support Catheters are single lumen catheters with a standard luer fitting hub and separate attachable hemostatic valve to support the CROSSER[®] CTO Recanalization Catheters 14S and S6. The product hub identifies SD for SIDEKICK[®] Catheter, USH for USHER[®] Catheter, A for Angled and T for Tapered in addition to the sheath profile and working length in centimeters. A guidewire introducer is provided to facilitate the guidewire passage through the optional hemostatic valve. The guidewire introducer shaft color matches the shaft color of the recommended support catheter.

The SIDEKICK[®] Catheter is available in straight, angled, tapered and non-tapered configurations in 70cm and 110cm working lengths. The USHER[®] Catheter is tapered and is available in straight and angled configurations in 83cm and 130cm working lengths. The SIDEKICK[®] and straight USHER[®] Catheters have a single radiopaque marker 1mm from the distal tip. The angled USHER[®] Catheter configurations have three radiopaque markers at the distal tip for enhanced visualization of the catheter tip and angle under fluoroscopy. The third proximal radiopaque marker is located 15mm from the distal tip.

The GEOALIGN[®] Marking System is a non-radiopaque ruler on the catheter shaft measured from the distal tip. The GEOALIGN[®] Markings are designated on the catheter shaft by 1cm increment bands with an accuracy within ± 1 mm. The distance from the distal catheter tip is labeled in 10cm increments. Thicker bands denote the midway point (5cm) between the labeled distances. The GEOALIGN[®] Marking System is designed to be used as a tool to externally measure the intravascular advancement and/or retraction of the catheter. This can provide an intravascular reference regarding the location of the distal tip of the catheter or an approximate intravascular length measurement between two points. The GEOALIGN[®] Marking System may also facilitate geographic alignment of an adjunctive therapy that includes the same GEOALIGN[®] Marking System.

6. Indications for Use of Device:

The SIDEKICK[®] and USHER[®] Support Catheters are single lumen catheters intended to create a pathway for other devices in the peripheral vasculature.

Contraindications

The SIDEKICK[®] and USHER[®] Support Catheters are contraindicated for use with cutting/scoring balloons, pediatrics, neonatal and neurovascular patients.

7. Technological Comparison to Predicate Devices:

The technological characteristics of the subject device are substantially equivalent to those of the predicate device because the two have the following similarities:

Special 510(k): Device Modification
SIDEKICK[®] and USHER[®] Support Catheters

- Same intended use
- Same indications for use
- Same patient population
- Same sheath compatibility
- Same fundamental scientific technology
- Same operating principal and mechanism of action
- Same packaging configuration
- Same sterility assurance level and method of sterilization

The subject device is a modification to the predicate device and is different as follows:

- The GEOALIGN[®] Marking System has been added to the device. The GEOALIGN[®] Marking System is a non-radiopaque ruler on the catheter shaft measured from the distal tip. The markings have the same intended purpose, use the same ink formulation, and ink application process as the previously cleared reference devices of the same regulation number, the ULTRAVERSE[®] 035 PTA Balloon Dilatation Catheter (K142261, cleared September 24, 2014, Regulation Number 870.1250) and the CROSSER[®] CTO Recanalization (K161208, cleared May 24, 2016, Regulation Number 870.1250).

8. Performance Testing Summary:

To demonstrate substantial equivalence of the subject device to the predicate device, the technological characteristics and performance criteria were evaluated. Using the FDA guidance document, "Design Control Guidance for Medical Device Manufacturers," dated March 11, 1997, and internal risk assessment procedures, the following non-clinical tests were performed:

- GEOALIGN[®] Marking Legibility
- Dimensional Analysis:
 - GEOALIGN[®] Marking Location (Distal Position)
 - GEOALIGN[®] Marking Location (Proximal Position)
 - GEOALIGN[®] Marking Spacing
 - Catheter Outer Diameter (OD)
- GEOALIGN[®] Marking durability with Introducer Sheaths
- GEOALIGN[®] Marking compatibility with Introducer Sheaths

The results demonstrate that the technological characteristics and performance criteria of the SIDEKICK[®] and USHER[®] Support Catheters are comparable to the predicate device and that it performs substantially equivalent to the legally marketed predicate device.

Per ISO 10993-1:2009 CORR 1, biocompatibility and chemical characterization demonstrate the subject device is biocompatible and does not elicit any substances at levels of concern as result of this change.

9. Conclusion:

The SIDEKICK® and USHER® Support Catheters are substantially equivalent to the legally marketed predicate devices, the SIDEKICK® and USHER® Support Catheters (K131493, cleared August 2, 2013).
