DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 27, 2017

Kalila Medical, Inc.
Carrie Neuberger
Regulatory Affairs
745 Camden Ave, Suite A
Campbell, California 95008-4146

Re: K162427
Trade/Device Name: Vado® Bi-Directional Steerable Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: December 20, 2016
Received: December 28, 2016

Dear Carrie Neuberger:

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.

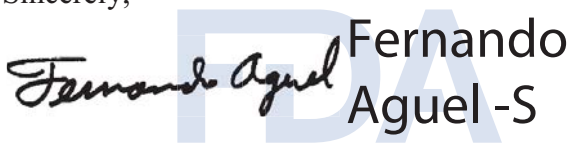
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



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)*
K162427

Device Name
Vado® Bi-Directional Steerable Sheath

Indications for Use *(Describe)*
The Vado® Bi-Directional Steerable Sheath is indicated for introducing various cardiovascular catheters into the vasculature and into the chambers of the heart including the left side of the heart through the interatrial septum.

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.

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510(k) Summary

510(k) Number	K162427	
Submitter Name and Address		
Name:	Kalila Medical, Inc.	
Address:	745 Camden Avenue, Suite A Campbell, CA 95008	
Telephone:	408-637-2150	
Fax:	408-370-6325	
Contact:	Carrie Neuberger	
Date Prepared:	December 20, 2016	
General Device Information		
Device Name:	Vado® Bi-Directional Steerable Sheath	
Common Name:	Catheter introducer	
Classification:	21 CFR 870.1340 A catheter introducer is a sheath used to facilitate placing a catheter through the skin into a vein or artery.	
Device Class:	Class II	
Product Code:	DYB	
Predicate Device		
Manufacturer	Device Name	510(k) Number
Kalila Medical	Vado Steerable Sheath	K140420
St. Jude Medical	Agilis NxT Steerable Introducer	K061363
Device Description		
The Vado® Bi-Directional Steerable Sheath consists of a dilator and steerable sheath which are designed to provide intracardiac access and flexible, stable catheter positioning in the cardiac anatomy. A hemostasis valve in the handle minimizes blood loss during catheter introduction and/or exchange. A side port with 3-way stopcock is provided for air or blood aspiration, fluid infusion, blood sampling and pressure monitoring. A deflection knob on the handle deflects the tip of the sheath clockwise ≥ 180° and counterclockwise ≥ 90°. Distal tip vent holes facilitate aspiration and a radiopaque marker permits visualization of the sheath tip under fluoroscopy.		
Indications for Use		
The Vado Bi-Directional Steerable Sheath is indicated for introducing various cardiovascular catheters into the vasculature and into the chambers of the heart including the left side of the heart through the interatrial septum.		
Comparison to the Predicate Device		
The Vado Bi-Directional Steerable Sheath has the same indications for use and intended use as the predicate devices. The Vado Bi-Directional Steerable Sheath		

utilizes the same or similar materials, design principals and fundamental scientific technology as the predicate device(s).

Device Characteristic	Subject Device: Vado Bi-Directional Steerable Sheath	Predicate Device: Vado Steerable Sheath (K140420)	Predicate Device: Agilis NxT Introducer (K061363)
Description	Dilator/introducer with hemostatic hub designed to introduce sheath into the vessel; steerable catheter introducer	Dilator/introducer with hemostatic hub designed to introduce sheath into the vessel; steerable catheter introducer	Dilator/introducer with hemostatic hub designed to introduce sheath into the vessel; steerable catheter introducer
Indications for Use	The Vado Bi-Directional Steerable Sheath is indicated for introducing various cardiovascular catheters into the vasculature and into the chambers of the heart including the left side of the heart through the interatrial septum.	The Vado Steerable Sheath is indicated for introducing various cardiovascular catheters into the vasculature and into the chambers of the heart including the left side of the heart through the interatrial septum.	The Agilis NxT Steerable Introducer is indicated when introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.
Intended Use	Catheter Introducer	Catheter Introducer	Catheter Introducer
Handle Deflection Mechanism	Rotary type deflection	Rotary type deflection	Rotary type deflection
Sheath French Size	8.8 Fr	8.8 Fr	8.5 Fr
Sheath Length (Total)	91 cm	83 cm	91 cm (and 81cm)
Dilator Length (Usable)	93 cm	85 cm	94 cm (and 85 cm)
Guide wire compatibility	0.032” max	0.032” max	0.032” max
Tip Deflection	Bi-Directional (180°/90°)	Uni-Directional (140°)	Bi-Directional (180°/90°)
Packaging Configuration	Tray inside pouch inside shelf carton	Tray inside pouch inside shelf carton	Tray inside pouch inside shelf carton
Sterilization	EO gas	EO gas	EO gas

Where design differences exist between the subject device and the predicate device, performance testing demonstrates that these differences do not adversely affect safety and effectiveness.

This submission supports the position the Vado® Bi-Directional Steerable Sheath, FG1_008, is substantially equivalent to the Vado Steerable Sheath (K140420) and the Agilis NxT Steerable Introducer (K061363).

Summary of Non-Clinical and Clinical Testing
The 510(k) notice contains summaries of device and packaging performance tests, shelf life tests, biocompatibility, and sterilization studies conducted to evaluate the performance characteristics of the Vado® Bi-Directional Steerable Sheath, FG1_008. The data presented demonstrates that the Vado® Bi-Directional Steerable Sheath met its functional and performance characteristics in accordance with applicable industry standards and is equivalent to the predicate devices. To verify the Vado® Bi-Directional Steerable Sheath met its functional and performance requirements, representative sterilized samples of the device underwent sterilization, biocompatibility, bench testing, packaging integrity, and shelf life testing. Biocompatibility Tests: 1. Cytotoxicity (MEM Elution) 2. Sensitization (Guinea Pig Maximization Sensitization) 3. Irritation (Intracutaneous Reactivity Irritation in Rabbits) 4. Acute Systemic Toxicity 5. Pyrogen (Materials Mediated in Rabbits) 6. Hemolysis (Direct Contact) 7. Hemolysis (Indirect Contact) 8. Complement Activation 9. Thrombosis Bench Performance Tests: 1. Radiopacity 2. Corrosion Resistance 3. Sheath and Dilator Visual Inspection 4. Sheath Dimension Inspection 5. Dilator Dimension Inspection 6. Sheath Deflection 7. Sheath Curvature Dimensions 8. Insertion and Deflection Cycling 9. Aspiration Air Ingress 10. Valve Leakage Resistance 11. Sheath Leakage Resistance 12. Device Preparation 13. Valve Integrity and Functionality 14. Shaft Torque Strength 15. Kink Resistance 16. Marker Band Location 17. Tensile Strength Packaging Integrity Tests:

1. Pouch Seal Strength 2. Gross Leak Detection Clinical testing is not provided in this submission.
Statement of Equivalence
The Vado Bi-Directional Steerable Sheath has the same indications for use and the same or similar technological characteristics as the predicate devices. Testing has demonstrated that the Vado Bi-Directional Steerable Sheath does not raise any new questions of safety and effectiveness. Based on this and the data provided in this pre-market notification, the subject device and the predicate devices have been shown to be substantially equivalent.