



Food and Drug Administration
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March 7, 2017

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

Re: K160721

Trade/Device Name: Vado Steerable Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: January 29, 2017
Received: January 31, 2017

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" (21CFR 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,

 Fernando Aguel -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Change Control Table, Change History

Change Control Table

Version	Document Author	Document Approver	Date Approved
1.00	Name, Title, Office	Name, Title, Office	MM/DD/YYYY

Complete Change Control Table (all versions) retained in SWIFT Docs.

Indications for Use

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 on last page
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510(k) Number *(if known)*
K160721

Device Name

Vado Steerable Sheath

Indications for Use *(Describe)*

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.

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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"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."

Section 5 510(k) Summary

510(k) Number	K160721	
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:	June 13, 2016	
General Device Information		
Device Name:	Vado 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
Device Description		
The Vado Steerable Sheath consists of an 8.8F (ID) sheath and dilator, which is designed to provide flexible catheter positioning in the cardiac anatomy. The steerable introducer includes a hemostasis valve to minimize blood loss during catheter exchange. A sideport with three-way stopcock is provided for aspiration, fluid infusion, blood sampling and pressure monitoring. A handle equipped with a deflection knob, deflects the sheath tip. The steerable introducer features distal vent holes for aspiration and radiopaque markers to facilitate visualization under fluoroscopy.		
Intended Use (Indications)		
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.		
Comparison to the Predicate Device		
The Vado Steerable Sheath has the same intended use and fundamental scientific technology as the predicate device, including biocompatibility, packaging, sterilization, and labeling. Where dimensional 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 modified Vado Steerable Sheath, FG1_007, is substantially equivalent to the Vado Steerable Sheath, FG1_005 (K140420).

Summary of Non-Clinical and Clinical Testing

The 510(k) notice contains summaries of bench performance tests, packaging performance tests, and biocompatibility studies to evaluate the performance characteristics of the modified Vado Steerable Sheath, FG1_007. The data presented demonstrate that the modified Vado Steerable Sheath meets its functional and performance characteristics in accordance with applicable industry standards and is equivalent to the predicate device.

To verify that the modified Vado 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.

GLP 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)

Bench Performance Tests:

1. Steerable Sheath and Dilator Visual Inspection
2. Steerable Sheath Dimension Inspection
3. Steerable Sheath Marker Band Location
4. Dilator Dimensional Inspection
5. Valve Leakage Resistance at 40kPa
6. Leakage Resistance at 300kPa
7. Device Preparation
8. Dilator Snap Disengagement
9. Dilator Insertion and Retraction
10. Shaft Deflection
11. Curvature Dimensions
12. Aspiration
13. Catheter Insertion Cycling and Flexion Cycling
14. Bend Radius to Kink
15. Corrosion Resistance
16. Junction Strengths
17. Torque and Turns to Failure

18. Radiopacity

Packaging Integrity Tests:

1. Pouch Seal Strength
2. Gross Leak Detection

Pre-Clinical testing is not provided in this submission.

Clinical testing is not provided in this submission.

The fundamental scientific technology and technological characteristics of the modified Vado Steerable Sheath are the same as the Vado Steerable Sheath (K140420) predicate device including mechanism of action, packaging, biocompatibility, sterilization, and labeling. Through bench performance testing it was demonstrated that the modified Vado Steerable Sheath is as safe, and is as effective as the predicate device, and does not raise any new questions of safety and effectiveness.

Statement of Equivalence

The Vado Steerable Sheath has the same indications for use and technological characteristics as the predicate device. Based on this and the data provided in this pre-market notification, the subject device and the predicate device have been shown to be substantially equivalent.