DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 12, 2017

Spyder Medical
Michael Webb
CEO/President
22521 Avenida Empresa, Suite 111
Rancho Santa Margarita, California 92688

Re: K162500
Trade/Device Name: Ostial Sprit Cannulae
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, Or Tubing
Regulatory Class: Class II
Product Code: DWF
Dated: December 7, 2016
Received: December 13, 2016

Dear Michael Webb:

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

510(k) Number (if known): K162500

Device Name:

Ostial Sprit Cannulae

Indications for Use:

Spyder Medical's Ostial Sprit Cannulae is indicated for use in delivery of cardioplegia solution directly to the coronary arteries during cardiopulmonary bypass surgery.

☑ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

General Information

Owner: Spyder Medical
22521 Avenida Empresa, Suite 111
Rancho Santa Margarita, CA 92688
949.533.9982

Contact Person: Michael Webb
CEO/President

Date Prepared: January 9th, 2017

Device Name

Trade: Ostial Sprit Cannulae
Common Name: Cannula
Classification Name: Cardiopulmonary bypass vascular catheter, cannula or tubing.
Device Classification: II

Predicate Device

Trade: Coronary Artery Perfusion Cannula with Self-Inflating Balloon
Manufacturer: Vitalcor, Inc.
510(k) Number: K030231

Device Description

The Ostial Sprit Cannulae is a single use, disposable medical device. It consists of three main components all of which are based on common thermoplastics. The majority of the device consists of a vinyl tube provided for in three varying sizes in diameter; 6, 9 & 10.5 Fr, as well as, two varying degrees of rigidity; standard and flexible. Proximally, the device is anchored with a vinyl female luer connector. Distally, the device terminates in a pre-shaped vinyl cuff purposely positioned over a thru hole within the tubing for purposes of receiving the perfused cardioplegia solution. The cuff is provided for in five varying diameters of 4, 5, 6, 7 & 8 mm. The device is provided for in either a straight or distally angled configuration. Technologically, cardioplegia solution is infused at the proximal end exiting the distal end. During infusion, the cuff receives perfusate within its inner lumen maintaining its shape/rigidity.

510(k) Summary

Intended Use of Device

The Ostial Sprit Cannulae is intended for use in delivery of cardioplegia solution directly to the coronary arteries during cardiopulmonary bypass surgery.

Technological Characteristics

Spyder Medical's Ostial Sprit Cannulae has technological characteristics; including design, material, dimensional and performance characteristics, which are substantially equivalent to the predicate device.

Non-Clinical Performance

The non-clinical performance evaluation consisted of both functional and integrity testing conducted in parallel between both Spyder Medical's Ostial Sprit Cannulae and its predicate device. Functional testing involved a fluid performance evaluation, as well as, the mechanical effect upon hemolysis exhibited by both Spyder Medical's Ostial Sprit Cannulae and its predicate device. Whereas the integrity testing consisted of a leak/burst analysis of the entire device followed by a tensile strength analysis of the bond between the proximal luer connector and its tubing.

The functional evaluation entailed a clinical simulation of fluid perfusion through the subject and predicate device along with a fluid dynamic analysis of pressure loss from the proximal to distal end at varying flow rates. Based on the results, the subject device outperformed the predicate device as it sustained lower levels of pressure for the same given flow rates.

Based on the mechanical hemolysis evaluation, there existed no biologically significant differences in the blood parameters between Spyder Medical's Ostial Sprit Cannulae and its predicate device. The percent hemolysis for both Spyder Medical's Ostial Sprit Cannulae and its predicate device were considered substantially equivalent and biologically insignificant.

Integrity test results of Spyder Medical's Ostial Sprit Cannulae were considered acceptable and substantially equivalent to its predicate device.

510(k) Summary

Summary

Taking into consideration that Spyder Medical's Ostial Sprit Cannulae has the same intended use, principle of operation, substantially equivalent technological and performance characteristics, Spyder Medical considers the Ostial Sprit Cannulae to be substantially equivalent to its predicate.