K083793

510(k) SUMMARY

APR 2 7 2009

Trade Name:	Steerable Guide Catheter
Common Name:	Catheter Introducer
Classification Name:	Class II, Catheter Introducer, 21 CFR 870.1340
Device Code:	DYB
Manufacturer's Name:	Evalve, Inc.
Manufacturer's Address:	4045 Campbell Avenue Menlo Park, CA 94025
Corresponding Official: Title: Address: Phone:	Karuna Velusamy Senior Regulatory Affairs Specialist 4045 Campbell Avenue Menlo Park, CA 94025 (650) 330-8100
Predicate Device(s):	K043084 Velocimed Premere™ Delivery Sheath K034025 NMT Medical Transseptal Sheath Set K002054 Appriva Medical X-SEPT Transseptal Sheath and Transition K970229 Arrow Transseptal Super Arrow-Flex™ Percutaneous Sheath Introducer Set K052644 St. Jude Swartz™ Braided Transseptal Guiding Introducer
Indication for Use:	The Evalve Steerable Guide Catheter is used for introducing various cardiovascular catheters into the left side of the heart through the interatrial septum.
Device Description:	The Steerable Guide Catheter consists of a Steerable Guide (Guide) and a Dilator. The Steerable Guide Catheter consists of a distal and proximal catheter shaft, a radiopaque tip ring, a handle with a steering knob, a hemostasis valve with a luer lock flush port, a Dilator with a single central lumen and an atraumatic distal tip. The central lumen of the Guide allows for aspiration of air and infusion of fluids such as saline, and serves as a conduit during introduction and or exchange of the Dilator and ancillary devices (e.g.

	catheters) that have a maximum diameter of .204". The atraumatic distal tip of the Steerable Guide Catheter is radiopaque to allow visualization under fluoroscopy. The Dilator consists of a shaft, an echogenic feature at the distal tip, a hemostasis valve with a flush port and an internal lumen designed to accept ancillary devices that have a maximum diameter of 0.035" (e.g. needles or guidewires).
Testing:	Testing of the Steerable Guide Catheter was completed to demonstrate that the device meets the specifications and performance characteristics, and is substantially equivalent to the predicate devices. The testing included Steerable Guide torque, bending range and leakage testing. For a complete list, please see Section 18. In addition, biocompatibility studies and sterilization validation were completed for the Steerable Guide Catheter.
Sterilization:	The Steerable Guide Catheter will be provided sterile and is intended for single use only.
Packaging and Labeling:	The Steerable Guide Catheter is packaged individually in a packaging tube followed by a double sealed Tyvek pouch, and boxed in a shelf-cardboard carton. Four Steerable Guide Catheter shelf-cartons are packaged together in a shipping-carton prior to being shipped to the sterilizer.
Substantial Equivalence:	The design, dimensional and physical characteristics and indication for use submitted in this pre-market notification demonstrate that the Steerable Guide Catheter is substantially equivalent to the predicate devices cleared under K043084, K034025, K002054, K970229 and K052644. The bench testing conducted on the device demonstrates that the Steerable Guide Catheter is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 7 2009

Evalve, Inc..
c/o Ms. Karuna Velusamy
Senior Regulatory Affairs Specialist
4045 Campbell Ave.
Menlo Park, CA 94025

Re: K083793
Trade/Device Name: Steerable Guide Catheter
Regulation Number: 21 CFR 870.1280
Regulation Name: Steerable Catheter
Regulatory Class: Class II
Product Code: DRA
Dated: April 17, 2009
Received: April 20, 2009

Dear Ms. Velusamy:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use Statement

510(k) Number (if known): K083793

Device Name: Steerable Guide Catheter

Indication for Use:

The Evalve Steerable Guide Catheter is used for introducing various cardiovascular catheters into the left side of the heart through the interatrial septum.

Prescription Use X AND/OR Over-The-Counter Use
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K083793