K133396

FEB - 6 2014

510(k) Summary per 21CFR §807.92

Submitter's information

Stereotaxis, Inc.
4320 Forest Park Ave, Suite 100
St. Louis, MO 63108
Contact: John Nadelin, VP Regulatory Affairs & Quality Systems
Phone: 314-678-6130

Device/ classification name

Device Name:	Vdrive™ with V-Sono™
Classification/Common name:	Wire, Guide, Catheter
Classification Number:	870.1330
Product Code:	DQX
Classification Panel:	Cardiovascular
Currently Marketed Substantially Equivalent Device:	Vdrive™ with V-Sono™ (K122659)

Device description

The Vdrive™ with V-Sono™ is comprised of three major components,

1. Vdrive™ Hardware - control box, adjustable arm, drive unit and support structure
2. Vdrive™ User Interface – combination of software driven (a) Tableside Controller and (b) dedicated Vdrive™ Controller
3. V-Sono™ Disposable Kit – Handle Clamps (w/catheter inserts), Telescoping Catheter Support and Drape. These components are disposable, sterile, single use devices.

Intended use

The Vdrive™ System is intended to stabilize, navigate and control compatible intracardiac echocardiography (ICE) catheters to facilitate visualization of cardiac structures during the performance of cardiac procedures when used in conjunction with Stereotaxis compatible V-Sono™ disposable sets in the Vdrive™ system. Compatible catheters at this time include Biosense Webster, Inc. Soundstar™ 3D Ultrasound Catheters and Acuson AcuNav™ Ultrasound Catheters. Other models of ICE catheters have not been tested with the Vdrive™ system.

Vdrive™ with V-Sono™ is indicated for remotely controlling the advancement, retraction, rotation and anterior-posterior deflection of compatible ultrasound catheters inserted into the right atrium.

Continued on next page

Appendix 1: 510(k) Summary per 21CFR §807.92, Continued

Technological characteristics

Device Characteristic	Proposed Vdrive™ with V-Sono™	Vdrive™ with V-Sono™ (K122659)
Location of Catheter tip	Right side of heart	Right side of heart
Placement of catheter	Manual placement by surgeon	Manual placement by surgeon
Catheter Retraction/ Advancement	Mechanical	Mechanical
Variable Speed	Yes	Yes
Catheter Movement	Continuous	Continuous
Emergency Stop Option	Manual	Manual
Manual Override	Yes	Yes
Single Use	Yes	Yes
Sterilization Method	EtO	EtO
Control of catheter movement	Mechanical	Mechanical
Compatible Catheters	BWI Soundstar 3D Ultrasound Catheters and Acuson AcuNav Ultrasound Catheters	BWI Soundstar 3D Ultrasound Catheters and Acuson AcuNav Ultrasound Catheters
No. axes of movement	3	3
Control Room User Interface	Yes	Yes
SW driven	Yes	Yes

Performance data

Changes were made under Design Controls to ensure that the modified device is as safe and effective as the predicate device and that the design outputs of the modified device meet the design input requirements. Performance testing for electrical safety, EMC compatibility and software verification and validation testing were performed.

Based upon the documentation presented in this 510(k) it has been demonstrated that the Vdrive™ with V-Sono™ device is safe and effective for its intended use.

Date summary prepared: October 31, 2013

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

February 6, 2014

Stereotaxis, Inc.
C/O Diane Horwitz, Ph.D.
Senior Regulatory Advisor
4320 Forest Park Avenue, Suite 100
St. Louis, MO 63108

Re: K133396
Trade/Device Name: Vdrive™ with V-Sono™
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: January 8, 2014
Received: January 8, 2014

Dear Dr. Horwitz:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Owen P. Faris -S

for

Bram D. 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: K133396

Device Name: Vdrive™ with V-Sono™

The Vdrive™ System is intended to stabilize, navigate and control compatible intracardiac echocardiography (ICE) catheters to facilitate visualization of cardiac structures during the performance of cardiac procedures when used in conjunction with Stereotaxis compatible V-Sono™ disposable sets in the Vdrive™ system. Compatible catheters include Biosense Webster, Inc. Soundstar™ 3D Ultrasound Catheters and Acuson AcuNav™ Ultrasound Catheters. Other models of ICE catheters have not been tested with the Vdrive™ system.

Vdrive™ with V-Sono™ is indicated for remotely controlling the advancement, retraction, rotation and anterior-posterior deflection of compatible ultrasound catheters inserted into the right atrium.

Prescription Use __X__ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen P. Faris -S
Date: 2014.02.06 15:21:02 -05'00'