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

December 18, 2014

Stereotaxis, Inc.
% Diana Horwitz, Ph.D., Rac
Regulatory Consultant
2995 Steven Martin Dr,
Fairfax, Virginia 22031

Re: K141530
Trade/Device Name: Vdrive, Vdrive with V-CAS, Vdrive Duo
Regulation Number: 21 CFR 870.1290
Regulation Name: Steerable Catheter Control System
Regulatory Class: Class II
Product Code: DXX, DQX
Dated: November 12, 2014
Received: November 12, 2014

Dear Diana Horwitz, Ph.D., Rac,

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 yours,

Melissa A. Torres -S

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)*
K141530

Device Name
Vdrive®
Vdrive® with V-CAS™
Vdrive Duo™

Indications for Use *(Describe)*

The Vdrive® system is intended to stabilize, navigate and remotely control:

• Compatible Intracardiac Echocardiography (ICE) catheters to facilitate visualization of cardiac structure during the performance of cardiac procedure when used in conjunction with the V-Sono™ disposable sets in the Vdrive® system,

• Compatible loop (circular) mapping catheters to facilitate movement of the catheter during the performance of electrophysiological procedures when used in conjunction with the V-Loop™ disposable sets in the Vdrive® system, and

• Compatible fixed curve transseptal sheaths and catheters to facilitate movement of the sheath and catheter when used in conjunction with the V-CAS™ disposable sets in the Vdrive® system and with the Niobe® Magnetic Navigation System (MNS).

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

The Vdrive® with V-Loop™ disposable is indicated to remotely control the advancement, retraction, rotation, tip deflection and loop size of compatible loop catheters inserted across the septum into the left atrium using conventional procedures. Compatible catheters at this time include Biosense Webster Lasso 2515 and Lasso 2515 NAV Circular Mapping Catheters. Other models of loop catheters have not been tested with the Vdrive® system.

The Vdrive® with V-CAS™ disposable is indicated for remotely controlling the advancement, retraction, and rotation of compatible fixed curve transseptal sheaths, and the advancement and retraction of compatible magnetic electrophysiology (EP) mapping and ablation catheters inside the patient's heart when used in conjunction with a Stereotaxis Magnetic Navigation System. Compatible fixed curve sheaths at this time include the St. Jude Medical® Transseptal Sheath and Swartz™ Braided Transseptal Sheath. Other models of transseptal sheaths and mapping/ablation catheters have not been tested with the Vdrive® system. Vdrive® with V-CAS™ is contraindicated for vascular access sites other than the groin. It is not intended to advance the EP mapping and ablation catheters through the coronary vasculature nor the coronary sinus. The transseptal sheath is not to be moved while the EP catheter is actively delivering therapy.

The Vdrive Duo™ is an optional accessory intended for remotely controlling the Vdrive® system when one arm of the device is equipped with one disposable set (V-Sono™, V-Loop™ or V-CAS™) and the other arm is equipped with a different available disposable set. During the procedure, the Vdrive Duo™ allows selection between the disposable sets.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

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 & Quality
Telephone: 314-678-6130

Device/ classification name

Device Name:	Vdrive®, Vdrive® with V-CAS™, Vdrive Duo™
Classification/Common name:	System, Catheter Control, Steerable
Classification Number:	870.1290
Product Code:	DXX, DQX
Classification Panel:	Cardiovascular
Predicate Devices:	• Cardiodrive® Catheter Advancement System, K071029 (Stereotaxis) • Vdrive® with V-Loop™, K140804 (Stereotaxis) • Vdrive® with V-Sono™, K122659 (Stereotaxis) • Vdrive Duo™, K133396 (Stereotaxis) • Artisan S Control Catheter, K090365 (Hansen Medical)

Device description

Vdrive® with V-CAS™ is intended to control a compatible fixed curve transseptal sheath and catheter during diagnostic and therapeutic cardiac procedures and is comprised of four major components:

1. Vdrive® Hardware - control box, adjustable arm, drive unit and support structure or Vdrive Duo™ (K133396) - with two adjustable arms
2. Vdrive® User Interface – combination of software-driven (a) Tableside Controller and (b) dedicated Vdrive® Controller
3. V-CAS™ Disposable Kit – Handle Clamps, Catheter Support Tube and Drape. These components are disposable, sterile, single use devices.
4. V-Loop™ Disposable Kit (K140804)
5. V-Sono™ Disposable Kit (K122659)

Intended use

The Vdrive® system is intended to stabilize, navigate and remotely control:

- Compatible Intracardiac Echocardiography (ICE) catheters to facilitate visualization of cardiac structure during the performance of cardiac procedure when used in conjunction with the V-Sono™ disposable sets in the Vdrive® system,
- Compatible loop (circular) mapping catheters to facilitate movement of the catheter during the performance of electrophysiological procedures when used in conjunction with the V-Loop™ disposable sets in the Vdrive®

STEREOTAXIS
Improving Life with Robotic Precision and Safety

system, and
- Compatible fixed curve transseptal sheaths and catheters to facilitate movement of the sheath and catheter when used in conjunction with the V-CAS™ disposable sets in the Vdrive® system and with the Niobe® Magnetic Navigation System (MNS).

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

The Vdrive® with V-Loop™ disposable is indicated to remotely control the advancement, retraction, rotation, tip deflection and loop size of compatible loop catheters inserted across the septum into the left atrium using conventional procedures. Compatible catheters at this time include Biosense Webster Lasso 2515 and Lasso 2515 NAV Circular Mapping Catheters. Other models of loop catheters have not been tested with the Vdrive® system.

The Vdrive® with V-CAS™ disposable is indicated for remotely controlling the advancement, retraction, and rotation of compatible fixed curve transseptal sheaths, and the advancement and retraction of compatible magnetic electrophysiology (EP) mapping and ablation catheters inside the patient's heart when used in conjunction with a Stereotaxis Magnetic Navigation System. Compatible fixed curve sheaths at this time include the St. Jude Medical® Transseptal Sheath and Swartz™ Braided Transseptal Sheath. Other models of transseptal sheaths and mapping/ablation catheters have not been tested with the Vdrive® system. Vdrive® with V-CAS™ is contraindicated for vascular access sites other than the groin. It is not intended to advance the EP mapping and ablation catheters through the coronary vasculature nor the coronary sinus. The transseptal sheath is not to be moved while the EP catheter is actively delivering therapy.

The Vdrive Duo™ is an optional accessory intended for remotely controlling the Vdrive® system when one arm of the device is equipped with one disposable set (V-Sono™, V-Loop™ or V-CAS™) and the other arm is equipped with a different available disposable set. During the procedure, the Vdrive Duo™ allows selection between the disposable sets.

STEREOTAXIS
Improving Life with Robotic Precision and Safety

Technological Characteristics

Device Character-istic	Subject Device Vdrive® with V-CAS™, Vdrive Duo™	Predicate 1 Cardiodrive® (K071029)	Predicate 2 Vdrive® with V-Loop™ (K140804)	Predicate 3 & 4 Vdrive® with V-Sono™ (K122659, K133396)	Predicate 5 Artisan S Control Catheter (K090365)
Location of Catheter tip	Right atrium or left atrium	Same	Same	Right atrium	Same
Initial Placement of catheter	Manual placement by electrophysiol ogist under fluoroscopy	Same	Same	Same	Same
Type of Procedure	Diagnostic or therapeutic EP procedures	Same	Diagnostic EP procedures	Cardiac imaging	Diagnostic EP procedures
Sheath Movements	Remote retraction and advancement, rotation	Does not control sheath (this is done manually)	N/A (no sheath)	N/A (no sheath)	Remote retraction, advance-ment, and *deflection*
Catheter Movements	Advance-retract Magnetic steering	Same	Advance/ retract, *rotation, deflection, loop size*	Advance/ retract, *rotation, deflection*	*None. Catheter is captured by sheath*
Visualiza-tion During Procedure	Fluoroscopy, standard of care	Same	Same	Same	Same
Catheter Tip Movement	Niobe (magnetic navigation)	Same	*Vdrive manipulation*	*Vdrive manipulation*	*Articulating sheath moves catheter tip*
Single Use Disposable	Sterile handle clamp Catheter Support Drape	Sterile Drive unit Bracket	Same	Same	Sheath cassette Irrigation manifold Drape

Performance data

Performance data establish the substantial equivalence of the Vdrive® with V-CAS™ compared to the predicate devices. Performance data included software verification and validation data, bench performance testing, animal testing, and reference to a prospective randomized multi-center clinical trial of the Vdrive® with V-Loop™ system in navigation of circular mapping catheters compared to conventional manual methods of navigation. Performance testing was conducted for electrical safety, EMC compatibility, sterilization and shelf life and packaging.

Animal Testing: Stereotaxis performed an animal study in a porcine model to evaluate the safety and effectiveness of Vdrive® with V-CAS™ to perform sheath and catheter movements according to product requirements, product usability and extremes of use. This study demonstrated that Vdrive™ with V-CAS™ met its performance and user requirements.

Clinical Testing: Stereotaxis performed a prospective, randomized multi-center clinical trial of the Vdrive® with V-Loop™ system compared to conventional manual methods of navigation in patients who underwent a pulmonary vein (PV) isolation procedure for treatment of atrial fibrillation (The VERSATILE Study, http://clinicaltrials.gov/show/NCT01656772). Out of the 120 enrolled subjects in this trial, investigators employed Vdrive Duo™ in 33 subjects, providing safety data on use of the combinations V-Loop™ + V-Sono™ (n=18) and V-Loop™ + V-CAS™ (n=15). V-Sono™ was used to control the Biosense Webster, Inc. Soundstar™ 3D Ultrasound Catheter; V-Loop™ was used to control the Lasso 2515 NAV Circular Mapping Catheter; and V-CAS™ was used to control compatible magnetic electrophysiology mapping and ablation catheters in conjunction with a Stereotaxis Magnetic Navigation System and the St. Jude Medical® Transseptal Sheath or the Swartz™ Braided Transseptal Sheath. Results of this study supported the safety and effectiveness of the Vdrive® system, including the use of Vdrive Duo™ with combinations of two disposables. Analysis of safety data showed that no adverse events related to the Vdrive® system occurred. Electrical PV isolation was achieved in 57/59 (96.6%) of targeted PVs using the ablation catheters controlled by the V-CAS™ disposable in the 15 subjects who underwent the ablation procedure using Vdrive Duo™ with V-CAS™.

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

Date summary prepared: December 16, 2014