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Appendix 1 – 510(k) Summary of Safety and Effectiveness

Statement	Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR §807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.
Device description	The Cardiodrive® advances or retracts a compatible magnetic electrophysiology [EP] mapping catheter, through a hemostasis introducer, remotely via a User Interface (UI) located either at the patient table or in the control room.
Intended use	The Stereotaxis Cardiodrive® is intended for automatically advancing and retracting only compatible magnetic electrophysiology [EP] mapping catheters. It is not intended to advance the EP mapping catheter through the coronary vasculature nor the coronary sinus.
Technological characteristics	The Stereotaxis Cardiodrive® consists of an electrical controller, motor assembly, and user controls, plus sterile, single-use advancer unit, patient mounting bracket, flexible drive shaft, and hemostasis valve adapter.
Performance data	Bench testing demonstrates that the Stereotaxis Cardiodrive® performs in an equivalent manner to the Stereotaxis Catheter Advancer System (CAS) predicate device.
Conclusion	The Stereotaxis Cardiodrive® is substantially equivalent to the Stereotaxis Catheter Advancer System (CAS) (021802) predicate device.
Contact	Gary M. Rauvola, Director, Regulatory Affairs for Disposable Products
Date	September 20, 2004

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 9 2006

Stereotaxis, Inc.
c/o Mr. Gary Rauvola, RAC
Director, Regulatory Affairs - Disposable Products
4320 Forest Park Avenue
Suite 100
St. Louis, MO 63108

Re: K042850
Trade/Device Name: Stereotaxis Cardiodrive® Catheter Advancer System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: June 12, 2006
Received: June 13, 2006

Dear Mr. Rauvola:

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix 2 - Indications for Use Statement

Statement

The indications for Use Statement:

510(k) Number: **K042850**_____

Device Name: Stereotaxis Cardiodrive®

Stereotaxis Cardiodrive®:
The Cardiodrive® is intended for automatically advancing and retracting only compatible magnetic electrophysiology [EP] mapping catheters inside the patient's heart when used in conjunction with a Stereotaxis Magnetic Navigation System [MNS]. It is not intended to advance the EP mapping catheter through the coronary vasculature nor the coronary sinus.

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)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K042850