K021802

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Appendix A: 510(k) Summary of Safety and Effectiveness (rev. 04-03-03)

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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 Stereotaxis Cardiodrive™ is a tool that provides the physician with the ability and the choice to advance and retract catheters either standing bedside, or from a control room.
Intended use	The Stereotaxis Cardiodrive™ is intended for automatically advancing and retracting only the Stereotaxis Tangent™ Electrophysiology Catheter (part # 001-001223-1) of 7F shaft diameter and 8F tip. The Cardiodrive™ is intended to advance the Stereotaxis Tangent™ Electrophysiology Catheter in the right side of the heart only. It is not intended to advance the Tangent™ Electrophysiology Catheter through the coronary vasculature nor the coronary sinus.
Technological characteristics	The Stereotaxis Cardiodrive™ consists of an electrically powered Controller, Motor, and User Interface, plus sterile single-use Advancer Unit, Patient Mounting Bracket, Flexible Drive Shaft, and Hemostasis Introducer Adapter.
Performance data	Bench testing and animal testing demonstrate that the Stereotaxis Cardiodrive™ performs in an equivalent manner to the Jomed Trak Back predicate device.
Conclusion	The Stereotaxis Cardiodrive™ is substantially equivalent to the Jomed Trak Back (K990271) and the IntraLuminal Therapeutics ILT Catheter (K001992) predicate devices.
Contact	Gary M. Rauvola, Director, Regulatory Affairs for Disposable Products
Date	April 3, 2003

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 0 8 2003

Stereotaxis, Inc.
c/o Mr. Gary M. Rauvola
Director, Regulatory Affairs for Disposable Products
4041 Forest Park Avenue
St. Louis, Missouri 63108

Re: K021802
Trade Name: Stereotaxis Cardiodrive
Regulation Number: 21 CFR 870.1250 and 870.1330
Regulation Name: Percutaneous Catheter and Catheter Guide Wire
Regulatory Class: Class II (two)
Product Code: DQY and DQX
Dated: January 24, 2003
Received: January 27, 2003

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 (301) 594-4646. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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 B: Indications for Use Statement

(rev. 04-03-03)

Statement

Indications for Use Statement:

510(k) Number: K021802

Device Name: Stereotaxis Cardiodrive™

Indications for Use: The Stereotaxis Cardiodrive™ is intended for automatically advancing and retracting only the Stereotaxis Tangent™ Electrophysiology Catheter (part # 001-001223-1) of 7F shaft diameter and 8F tip. The Cardiodrive™ is intended to advance the Stereotaxis Tangent™ Electrophysiology Catheter in the right side of the heart only. It is not intended to advance the Tangent™ Electrophysiology Catheter through the coronary vasculature nor the coronary sinus.

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K021802

Prescription Use ✓