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

K043457

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 Assert™ Guide Wire is a steerable guide wire that has a nominal diameter of 0.014 in/ 0.36mm and nominal lengths of 180 cm and 300 cm. The guide wire is designed only for use in conjunction with the Stereotaxis Magnetic Navigation System. The wire is configured with a tapered distal tip and an embedded magnet, which is used for navigating the wire through the vasculature. A hydrophilic coating covers the distal portion of the wire, and a PTFE coating covers the proximal end of the wire. This device is sterilized with 100% ethylene oxide.

Technological characteristics

The Assert™ Guide Wire is a conventional 0.014" coated endovascular guide wire modified to accommodate magnetic actuation and control. It is designed to navigate within the vasculature to deliver a suitable catheter or interventional device to a desired site.

The finished lengths of the guide wire are 180cm and 300cm. A taper runs proximal to the distal tip. The pushable shaft is a continuous wire that allows axial force, applied at the proximal end, to be transmitted to the tip of the guide wire. The guide wire is used with an introducer sheath to access the human vasculature.

Intended use

Indications for Use: The Stereotaxis Assert™ Guide Wire is intended to introduce and position over-the-wire catheters and other over-the-wire therapeutic devices within the coronary and peripheral vasculature during PTCA or other intravascular interventional procedures.

Contraindications: This guide wire is not intended for use without the Stereotaxis Magnetic Navigation System. The device is not intended for use in the cerebral vasculature. Rotational atherectomy devices, and any ferromagnetic interventional devices, are contraindicated for use with the Stereotaxis Assert™ Guide Wires.

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Appendix 1: 510(k) Summary of Safety and Effectiveness,
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Device comparisons	The Stereotaxis Assert™ Guide Wire is a minor design modification of the currently marketed Stereotaxis Endovascular Guide Wire. The new wire has a modified taper to the core wire profile, has a different hydrophilic coating on the distal end, and carries a PTFE coating on the proximal end.
Physical testing	The Stereotaxis Assert™ Guide Wire was designed and tested in compliance with the FDA "Coronary and Cerebrovascular Guidewire Guidance" dated January 1995. The device met design input criteria and was substantially equivalent to the currently marketed predicate device.
Preclinical animal performance data	Testing of the Stereotaxis Assert™ Guide Wire in the swine animal model demonstrated substantial equivalence to the currently marketed predicate device.
Clinical performance data	No clinical studies were needed to support the modifications.
Substantial equivalence	The Assert™ Guide Wire is a substantially equivalent modification of the Stereotaxis Endovascular Guide Wire originally cleared under K021363. The modifications described herein do not affect the intended use of the device or alter the fundamental scientific technology associated with the device.
Contact	Gary M. Rauvola, RAC Director, Compliance & Regulatory Affairs Stereotaxis, Inc. 4041 Forest Park Avenue St. Louis, Missouri 63108 Ph. 314-615-6913 Fax 314-615-6912
Date	December 09, 2004

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 28 2005

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

Re: K043457
Stereotaxis Assert™ Endovascular Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: II
Product Code: DQX
Dated: February 10, 2005
Received: February 11, 2005

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vachner

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

Enclosure

Appendix 2: Revised Indications for Use Form

Indications for Use Statement

510(k) Number K043457:

Device Name: Assert™ Guide Wires

Indications for Use: Stereotaxis Assert™ Guide Wires are intended to introduce and position over-the-wire catheters and other over-the-wire therapeutic devices within the coronary and peripheral vasculature during PTCA or other intravascular interventional procedures.

Contraindications: This guide wire is not intended for use without the Stereotaxis Magnetic Navigation System. The device is not intended for use in the cerebral vasculature. Rotational atherectomy devices, and any ferromagnetic interventional devices, are contraindicated for use with Stereotaxis Assert™ Guide Wires.

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

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Donna R Kucharczyk

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K043457