JUL - 1 2004

510(k) Summary of Safety and Effectiveness, K032937

Statement

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, regarding safety and effectiveness is summarized below. This summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR Part 807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

Device description

The Niobe® Magnetic Navigation System [NMNS] is an interventional workstation for the navigation of appropriately equipped, magnetically adapted, devices (e.g., catheters or guidewires) through tissue to designated target sites. The system uses computer-controlled permanent magnets for orienting the tip of a magnetic device.

The system employs magnetic fields to *orient* or *steer* the tip of a magnetic device.

The Navigant Navigation Workstation 2.1 [NWS2] is a modification to the Niobe® Magnetic Navigation System (K021555). The changes introduce a new software design and mode of operation, but maintain the existing technology for orientation of magnetically-adapted devices and clinical utility.

The NWS2 is a subsystem of the MNS, and requires both an MNS and a digital fluoroscopy system to function properly.

Intended use

The Navigant™ Navigation Workstation 2.1 [NWS2] is a component of the Niobe® MNS. The Niobe® MNS with NWS2 is intended to navigate compatible magnetic devices through tissue to designated target sites in the right and left heart and coronary vasculature by orienting the device tip in a desired direction. The Navigant™ feature provides an enhanced navigation interface for the physician to control the MNS.

Substantial equivalence

The Niobe® MNS with NWS2 is substantially equivalent to the Telstar® Magnetic Navigation System [TMNS] (K013484), and the NMNS (K021555).

Continued on next page

510(k) Summary of Safety and Effectiveness, K032937,
Continued

Technological characteristics

The Niobe® Magnetic Navigation System employs application of magnetic fields to orient the distal tip of a magnetically-adapted device (e.g., catheter or guidewire).

Device comparisons – steering control

The following is a comparison of the key features of the Niobe® MNS with NWS2 vs. the predicate device, the Niobe® MNS, K021555.

Device Characteristics	New Device- Niobe® MNS with NWS2	Predicate Device- Niobe® MNS
Intended use	To navigate compatible magnetic devices through tissue to designated target sites in the right and left heart and coronary vasculature by orienting the device tip in a desired direction.	To navigate a magnetic device through tissue to designated target sites in the right and left heart and coronary vasculature by orienting the device tip in a desired direction.
Direct contact with patient tissue	No	No
Remote physician control of steerable device distal orientation	Yes	Yes
Computer control of steerable device distal orientation	Yes	Yes
Conducted under fluoroscopic visualization	Yes	Yes
Guided magnetic device employed	Specially designed magnetic catheters/guidewires	Specially designed magnetic catheters/guidewires
Steering control	Via magnetic fields, from a control room or at patient table side	Via magnetic fields, from a control room or at patient table side

Continued on next page

510(k) Summary of Safety and Effectiveness, K032937,
Continued

Device comparisons – steering control (continued)

Device Characteristics	New Device- Niobe® MNS with NWS2	Predicate Device- Niobe® MNS
System command	Physician-directed computer command	Physician-directed computer command
Magnetic field source	Two permanent magnets – positioned mechanically	Two permanent magnets – positioned mechanically
Operating field strength	Up to 0.10 T	Up to 0.10 T

Physical testing

Performance testing has demonstrated substantial equivalence of the new device to the predicate device.

Preclinical animal and clinical performance data

The Navigant™ Navigation Workstation 2.1 [NWS2] is a modification of the predicate Niobe® MNS. Animal and clinical data are not necessary to support the modifications. Application data (animal and clinical) for magnetic navigation were provided in K013484 & K021555.

Contact

Peter A. Takes, Ph.D., RAC
Director, Clinical & Regulatory Affairs
Stereotaxis, Inc.
4041 Forest Park Avenue
St. Louis, Missouri 63108
Ph. 314-615-6964
Fax 314-615-6912
takesp@stereotaxis.com

Date

June 28, 2004

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 1 2004

Stereotaxis, Inc.
c/o Peter A. Takes, Ph.D., RAC
Director
Clinical and Regulatory Affairs
4041 Forest Park Avenue
St. Louis, Missouri 63108

Re: K032937
Trade Name: Navigant™ Navigation Workstation 2.1 (NWS2)
Regulation Number: 21 CFR 870.1290
Regulation Name: Steerable Catheter Control System
Regulatory Class: Class II (two)
Product Code: 74 DXX
Dated: May 6, 2004
Received: May 7, 2004

Dear Dr. Takes:

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.

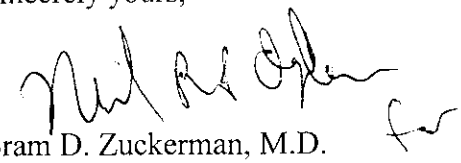
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 594-4648. 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

Indications for Use

510(k) Number (if known):___K032937

Device Name:___Navigant™ Navigation Workstation 2.1 [NWS2]

Indications For Use:

The Navigant™ Navigation Workstation 2.1 [NWS2] is a component of the Niobe® MNS. The Niobe® MNS with NWS2 is intended to navigate compatible magnetic devices through tissue to designated target sites in the right and left heart and coronary vasculature by orienting the device tip in a desired direction. The Navigant™ feature provides an enhanced navigation interface for the physician to control the MNS.

Prescription Use ___√__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K032937