Appendix 1: 510(k) Summary per 21CFR §807.92

Submitter's information

Stereotaxis, Inc.
4320 Forest Park Ave, Suite 100
St. Louis, MO 63108
Contact: Dennis Pozzo, Regulatory Affairs Specialist
Phone: 314-678-6136

OCT 19 2006

March 22, 2006

Device/ classification name

- Device Name:
  - Niobe® MNS w/Navigant™ NWS
- Classification/Common name:
  - Steerable Catheter Control System & Stereotaxic Instrument
- The marketed device(s) to which substantial equivalence is claimed:
  - Stereotaxis Guidewire and Stereotaxis Telstar® Magnetic Navigation System [MNS]
  - Navigant™ Navigation Workstation [2.1] [NWS2]
  - Stereotaxis Niobe® Magnetic Navigation System

Device description

The Stereotaxis Niobe® MNS with Navigant™ NWS is an interventional workstation for the intravascular 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. It is important to note that the system employs magnetic fields only to *orient* or *steer* the tip of a magnetic device.

Intended use

The Niobe® MNS with Navigant™ NWS is intended to navigate a magnet-tipped device through tissue to designated target sites in the right and left heart, coronary vasculature, neurovasculature and peripheral vasculature by orienting the device tip in a desired direction.

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Appendix 1: 510(k) Summary per 21CFR §807.92, Continued

Technological characteristics

The Niobe® MNS with/Navigant™ NWS with expanded indications is substantially equivalent to the predicate Niobe® MNS with/Navigant™ NWS in that:

1. The mechanical function and hardware of the existing Niobe® MNS with/Navigant™ NWS, will remain as is today.
2. They are intended to navigate compatible magnetic devices through tissue to designated target sites in any direction, without pre-shaping the tip prior to vessel insertion.

The Niobe® MNS with/Navigant™ NWS with expanded indications is substantially equivalent to the predicate Telstar® MNS in that:

1. They are intended to navigate compatible magnetic devices through tissue to designated target sites in any direction, without pre-shaping the tip prior to vessel insertion.
2. They have the same intended use, to navigate a magnet-tipped device through tissue to designated target sites in the right and left heart, coronary vasculature, neurovasculature and peripheral vasculature by orienting the device tip in a desired direction.
3. They have the same operating field strength, 0.15 Tesla.

Performance data

A Clinical Study was performed using the Stereotaxis Telstar® MNS and Cronus® Guidewires to demonstrate the safety and efficacy of magnetically guided devices when used in the neurovasculature. Stereotaxis is of the position that this clinical is applicable to support substantial equivalence of the Niobe® MNS with/Navigant™ NWS. The rationale for this position is based upon the success of the Telstar® MNS demonstrating clinical safety and efficacy of utilizing magnetic navigation with magnetic guidewires in the neurovasculature.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Stereotaxis, Inc.
% Mr. Dennis Pozzo
Regulatory Affairs Specialist
4320 Forest Park Avenue, Suite 100
St. Louis, Missouri 63108

OCT 19 2006

Re: K060967
Trade/Device Name: Stereotaxis® Niobe® Magnetic Navigation System (MNS) with Navigant™ Navigation Workstation (NWS)
Regulation Number: 21 CFR 870.1290
Regulation Name: Steerable catheter control system
Regulatory Class: II
Product Code: NDQ
Dated: September 28, 2006
Received: September 29, 2006

Dear Mr. Pozzo:

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.

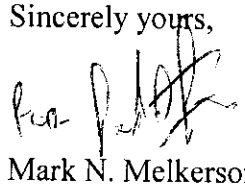
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0115. 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,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological 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: K060967

Device Name: Stereotaxis ® Niobe® Magnetic Navigation System (MNS) with Navigant™ Navigation Workstation (NWS)

The Niobe® MNS with Navigant™ NWS is intended to navigate compatible magnetic devices through tissue to designated target sites in the right and left heart, coronary vasculature, neurovasculature and peripheral vasculature by orienting the device tip in a desired direction.

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 General, Restorative, and Neurological Devices

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