K072371

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
August 14, 2007

NOV 14 2007

Device/ classification name

- Device Name:
  - Odyssey Workstation
- Classification/Common name:
  - Steerable Catheter Control System
- The marketed device(s) to which substantial equivalence is claimed:
  - Stereotaxis, Niobe MNS w/Navigant NWS
  - Navigant Workstation w/Niobe Magnetic Navigation System, Version NWS05
  - Navigant Navigation Workstation 2.1
  - Stereotaxis Niobe Magnetic Navigation System

Device description

The Odyssey Workstation is an optional (large screen) display and user interface package designed to augment the Navigation software system. The Odyssey Workstation allows the clinician to view multiple diagnostic tool screens (e.g. Navigant, X-Ray, ECG, Carto, etc.) in the catheter lab. on one large flat panel monitor to view and interpret a variety of sources on a single screen. There are multiple view formats available, and the clinician can customize layouts to facilitate their specific workflow.

Intended use

The Odyssey Workstation is an optional display and user interface package designed to consolidate the point of control in the Catheter Lab.

Continued on next page

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

Technological characteristics

The table below lists device characteristics of the proposed Odyssey Workstation vs. the predicate Navigant NWS.

Device Characteristic	Proposed Odyssey Workstation	Predicate Niobe MNS w/Navigant NWS
Display (monitor) Size	46"	23"
Pixel Resolution	1920 x 1080	1920 x 1200
Allowable Video Sources	12	2
Allows control of connected video sources.	Yes	One video source is controllable the other is not.
Keypad controls only Navigant	Yes	Yes
Allows control of video sources' native keypad and mouse.	Yes	Yes
Displays graphics & verbiage of connected video sources.	Yes	Yes
Allows the user to choose between predetermined layout/scripts or a customizable display.	Yes	Yes
Allows user interaction between video sources on the display.	Yes	Yes
Save display layout	Yes	Yes
Print display layout	No	Yes

Performance data

Based upon the documentation presented in this 510(k) it has been demonstrated that the Odyssey Workstation is safe and effective when used with the Niobe MNS w/Navigant NWS.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 14 2007

Stereotaxis, Inc.
c/o Mr. Dennis Pozzo
Regulatory Affairs Specialist
4320 Forest Park Avenue, Suite 100
St. Louis, MO 63108

Re: K072371
Trade/Device Name: Odyssey Workstation, Model 00-007000-1
Regulation Number: 21 CFR 870.1290
Regulation Name: Steerable Catheter Control System
Regulatory Class: Class II (two)
Product Code: DXX
Dated: August 22, 2007
Received: August 23, 2007

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.

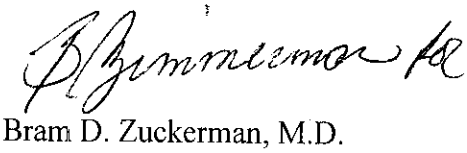
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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: K 072371

Device Name: Odyssey™ Workstation

The Odyssey Workstation is an optional display and user interface package designed to consolidate the point of control in the Catheter Lab.

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)

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(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K072371