4100 E. Milham Avenue
Kalamazoo, MI 49001
t: 269 323 7700 f: 800 965 6505
www.stryker.com

stryker
Instruments

K062640

510(k) Summary

Device Sponsor:

Stryker Instruments
4100 E. Milham Avenue
Kalamazoo, MI 49001
(p) 269-323-7700
(f) 269-324-5412

DEC 14 2006

Registration No.: 1811755

Trade Name: Stryker Navigation System – Cranial Module

Common Name: Navigation System

Classification Name: Stereotaxic Instruments

Equivalent to:

K993239 Stryker Navigation – Neuro Module
K002732 Stryker Navigation – ENT Module
K050438 Medtronic StealthStation System

Device Description:

Stryker Navigation System – Cranial Module is part of the product series of the Stryker Navigation System. The system comprises software for pre-operative surgical planning and supports computer assisted surgery based on a wireless optical tracking localization device for the use in navigated cranial surgery.

The Stryker Navigation Cranial Module is a combination of the previously cleared Stryker Navigation System – Neuro Module and ENT Module with the addition of new features. The Cranial module will include automatic multi-modality correlation. The system provides an easy-to-use work flow concept for image importation, FESS, Craniotomy, Biopsy, etc. Additional, automatic segmentation of brain surface, tumor, vessels, etc. are supported.

Intended Use:

Stryker Navigation System – Cranial Module
The Stryker Navigation System – Cranial Module is intended as a planning and intraoperative guidance system to enable open or percutaneous computer assisted surgery. The system is indicated for any medical condition in which the use of computer assisted planning and surgery may be appropriate. The system can be used for intra-operative guidance where a reference to a rigid anatomical structure can be identified.

Indications for Use:

The system should be operated only by trained personnel such as orthopedic surgeons and clinic staff. The Cranial Navigation system supports, but is not limited to, the following surgical procedures:

ENT Procedures

- Endoscopic Sinus Surgery (ESS)
- Intranasal procedures

- Ear implant procedures

Neuro Procedures

- Cranial biopsies
- Puncture of abscesses
- Craniotomies
- Craniectomies
- Resection of tumors and other lesions
- Removal of foreign objects
- Skull base procedures
- Transnasal neurosurgical procedures
- Transsphenoidal pituitary surgery
- Shunt placement, including pediatric shunt placement
- Placement of electrodes for recording, stimulation and lesion generation
- Craniofacial procedures
- Skull reconstruction procedures
- Orbital cavity reconstruction procedures

Contraindications

- Surgical situation where increasing surgical time may be detrimental to the patient.

Substantial Equivalence (SE) Rational:

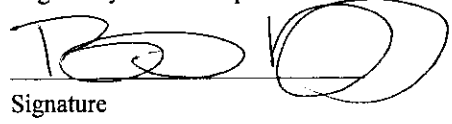
The Stryker Navigation System – Cranial Module is equivalent in intended use, safety, and effectiveness to existing devices being marketed by Stryker and Medtronic.

Safety and Effectiveness:

The Stryker Navigation System – Cranial Module does not raise any new safety and efficacy concerns when compared to similar devices already legally marketed. Therefore, the Stryker Navigation System – Cranial Module are substantially equivalent to these existing devices. They will be designed and manufactured in accordance with Stryker Leibinger's and Stryker Instrument's Quality Management System covered by QSR 21CFR 820.

Submitted by:

Becky Ditty
Regulatory Affairs Representative



Signature

Date submitted:

9/5/06

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 22 2007

Stryker Corporation
% Ms. Becky Ditty
Regulatory Affairs Representative
Stryker Instruments Division
4100 E Milham Ave
Kalamazoo, MI 49001

Re: K062640
Trade/Device Name: Stryker Navigation System – Cranial Module
Regulation Number: 21 CFR § 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: December 14, 2006

Dear Ms. Ditty:

This letter corrects our substantially equivalent letter of December 14, 2006.

We have reviewed your Section 510(k) pre-market 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 (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.

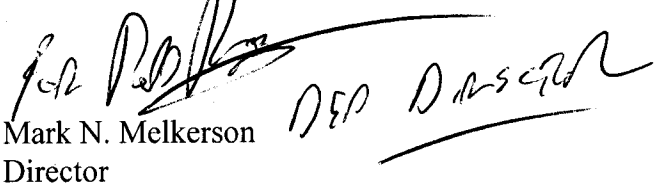
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 continue marketing your device as described in your Section 510(k) pre-market 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/dsma/dsmamain.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

510(K) Number (if known): ~~K060313~~ K062640

Device Name: Stryker Navigation System – Cranial Module

Intended Use

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- Transphenoidal pituitary surgery
- Shunt placement, including pediatric shunt placement
- Placement of electrodes for recording, stimulation and lesion generation
- Craniofacial procedures
- Skull reconstruction procedures
- Orbital cavity reconstruction procedures

Contraindications

- Surgical situation where increasing surgical time may be detrimental to the patient.

Prescription Use X and/or Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of General, Restorative, and Neurological Devices

510(k) Number K062640