750 Trade Centre Way
Suite 200
Portage, MI 49002
t: 269 324 5346 f: 877 648 7114
www.stryker.com

stryker

510(k) Summary of Safety and Effectiveness:

Stryker Universal Neuro 3 System

OCT 17 2013

Proprietary Name:	Stryker Universal Neuro 3 System
Common Name:	Neuro Plating System
Classification Name and Reference:	Preformed alterable cranioplasty plate - 21 CFR §882.5320 Burr hole cover - 21 CFR §882.5250 Cranioplasty plate fastener - 21 CFR §882.5360
Regulatory Class:	Class II
Device Product Code(s):	GWO, GXR and HBW
Predicate devices:	1. Stryker Universal Neuro 3 System (K112557) 2. Stryker QuikFlap Sterile Procedure Pack (K120352)
510(k) Contact Person:	Manish Patel Stryker Craniomaxillofacial 750 Trade Centre Way, Suite 200 Portage, MI 49002 Phone: 269-389-4271 Fax: 877-648-7114 manish.patel@stryker.com
Date Prepared:	June 14, 2013

Introduction:

This Special 510(k) is being submitted to the U.S. FDA to grant clearance to market the Stryker Universal Neuro 3 System cleared via K112557 with the proposed modifications.

Proposed Modifications:

The only modifications to the existing Stryker Universal Neuro 3 system are:

1. Change in sterility and packaging to offer the existing cleared implants in a sterile fashion in addition to the current non-sterile version.
2. Addition of MRI conditional statement to the IFU of the device.

Intended Use:

The Stryker Universal Neuro 3 System is intended for reconstruction, stabilization and/or rigid fixation of non load-bearing areas subsequent to craniotomy, craniectomy and cranial fractures in adults and adolescents (age 12 and higher).

Device Description:

The Stryker Universal Neuro 3 System comprises of an aluminum module which houses a comprehensive selection of plates, meshes, screws and instrumentation needed to fixate cranial bone flaps. Currently, all devices are provided non-sterile and require cleaning and sterilization prior to implantation. All implants (plates and screws) are single use devices whereas all instruments except for drills (screwdriver handle, blade) can be re-used.

Technological Characteristics:

The subject Stryker Universal Neuro 3 System when provided sterile with MRI conditional statement, will have the exact same design as its predicate version. Both subject and predicate devices will offer the same set of plates and screws in same dimensional specifications. There will be no change in material compositions as well. All plates and screws will be fabricated from commercially pure grades of titanium.

Summary of Performance testing:

Various verification and validation activities were performed based on results of the risk analysis to demonstrate that the design outputs of the modified device meets the design input requirements. Activities included - Sterilization Validation to ensure a sterility assurance level of 10^{-6}; Residual, Pyrogenicity and Cytotoxicity testing to assure reliable cleaning of the devices; Packaging and sealing validation to assure that sterility is maintained throughout shelf life taking into account shipping stresses and lastly, MRI compatibility to study displacement force, torque, artifacts and heating under magnetic resonance environment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 17, 2013

Stryker Craniomaxillofacial
Mr. Manish Patel
Senior Regulatory Compliance Analyst
750 Trade Centre Way, Suite 200
Portage, MI 49002

Re: K131775
Trade/Device Name: Stryker Universal Neuro 3 System
Regulation Number: 21 CFR 882.5320
Regulation Name: Preformed alterable cranioplasty plate
Regulatory Class: Class II
Product Code: GWO, GXR, HBW
Dated: July 18, 2013
Received: July 19, 2013

Dear Mr. Patel:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131775

Device Name: Stryker Universal Neuro 3 System

Indications For Use:

The Stryker Universal Neuro 3 System is intended for reconstruction, stabilization and/or rigid fixation of non load-bearing bony areas subsequent to craniotomy, craniectomy and cranial fractures in adults and adolescents (age 12 and higher).

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S