DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 24, 2015

Stryker Craniomaxillofacial
Mr. Jonathan Schell
Senior Regulatory Compliance Specialist
750 Trade Centre Way, Suite 200
Portage, Michigan 49002

Re: K151387
Trade/Device Name: Stryker Universal Neuro III System: UN III AXS Screw, UN III AXS Screwdriver Blade
Regulation Number: 21 CFR 882.5360
Regulation Name: Cranioplasty Plate Fastener
Regulatory Class: Class II
Product Code: HBW, GWO, GXR
Dated: May 22, 2015
Received: May 26, 2015

Dear Mr. Schell:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Stryker Universal Neuro III System: UN III AXS Screw, UN III AXS Screwdriver Blade

Indications for Use *(Describe)*
The Stryker Universal Neuro III 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).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Section 5. 510(k) Summary

This section provides a summary of 510(k) information in accordance with the requirements of 21 CFR 807.92.

I. SUBMITTER

510(k) Owner:	Stryker Leibinger GmbH& Co. KG Boetzinger Strasse 41 D-79111 Freiburg, Germany
Submitter/ Contact Person:	Jonathan Schell Sr. Regulatory Affairs Specialist Stryker Craniomaxillofacial 750 Trade Centre Way Portage, MI 49002 Phone: 269-389-5596 Fax: 877-648-7114
Date prepared:	May 22, 2015

II. DEVICE

Trade Name:	Stryker Universal Neuro III System (also referred to as Universal Neuro 3 System): UN III AXS Screw, UN III AXS Screwdriver Blade
Common or Usual name:	Neuro Plating System
Classification name:	Cranioplasty Plate Fastener 21 CFR §882.5360 Preformed alterable cranioplasty plate 21 CFR §882.5320 Burr hole cover 21 CFR §882.5250
Regulatory Class:	Class II
Product Code:	HBW, GWO, GXR

III. PREDICATE DEVICE

Predicate: Stryker Universal Neuro III System – K112557

This predicate has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The Stryker Universal Neuro III System (UN III) 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 or higher). The UN III System consists of an implant module for the respective anatomical and indicated areas with each containing various screw, and plate versions and shapes. This special 510(k) is being submitted due to dimensional modifications to the screw and screwdriver blade. There have been no modifications to the plates, meshes, or other accessory devices. The following Table 5-1 lists the devices subject to this Special 510(k):

TABLE 5-1 – LIST OF SUBJECT DEVICES

Article Number	Description
62-15035	AXS Screwdriver Blade Long
62-15036	AXS Screwdriver Blade Short
56-15034 56-15035 56-15036 56-15933 56-15934 56-15935 56-17334	AXS Screw
29-56034 29-56035 29-56933 29-56934 29-56935	Preloaded AXS Screw Disc

V. INDICATIONS FOR USE

The Stryker Universal Neuro III 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).

The proposed modifications do not alter the Indications for Use statement for the proposed device. The Indications for Use is identical to the predicate device Stryker Universal Neuro III System (K112557).

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The modified Universal Neuro III System is compared to its predicate device for substantial equivalence of technological characteristics based on the following criteria:

A. Principle of Operation
B. Technological Characteristics

A. Principle of Operation

The basic operational principle of the Stryker Universal Neuro III System (UN III) remains the same: the operating principle for the UN III system is to reconstruct, stabilize and/or provide rigid fixation of non load-bearing areas. Subsequently, the principle of operation of the modified screw device and the screwdriver blade accessory remain the same as the predicate device.

B. Technological Characteristics

The dimensional modification described in this special 510(k) is to the UN III System screw and screwdriver blade accessory. However, the modifications to the UN III screw and screwdriver blade accessory do not alter the technological and operational characteristics of the screw and the screwdriver blade accessory. The technological characteristics remain the same:

- Same operating principle: reconstruct, stabilize and/or provide rigid fixation of non load-bearing bony areas
- Same mode of fixation: plate fixation with screws
- Same area of contact and contact duration: the screws have contact to tissue/bone with a duration greater than 30 days; the blades, at worst, may contact breached or compromised surface for less than 24 hours
- Same material: Screw made from titanium alloy (ASTM F136) the blades are made from stainless steel (ASTM F899),

- Similar design: The modifications to the UN III screw and screwdriver blade accessory are dimensional specifications.

VII. PERFORMANCE DATA

Based on the Risk Analysis performed on the modifications to the UN III screw device and the modification to the screwdriver blade accessory, bench testing was performed in support of the substantial equivalence determination.

Biocompatibility and sterility testing was not required as a basis for substantial equivalence. There is no change in the material, manufacturing process, duration or location of contact, or reprocessing methods.

Performance Bench Testing

The following performance bench tests were completed.

- Self-Retention Test
- Screw Insertion Test
- Life Cycle Test – Fatigue (Screwdriver Blade)
- Torque to Failure Test – Quasi Static (Screwdriver Blade)
- End User / End Product Test

The subject device met all pre-defined acceptance criteria. Overall, the results of the performance bench tests support the proposed substantial equivalence of the subject device.

Animal Testing

Animal testing was not required as a basis for substantial equivalence.

Clinical Testing

Clinical testing was not required as a basis for substantial equivalence.

VIII. CONCLUSIONS

The results of the non-clinical data demonstrate that the modified UN III screw and screwdriver blade will perform as intended in the specified use conditions. According to the comparison based on the requirements of 21 CFR 807.87 and the information provided herein, it is concluded that the information included in this submission supports substantial equivalence.