DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 19, 2017

Stryker Craniomaxillofacial
Jonathan Schell
Staff Regulatory Affairs Specialist
750 Trade Centre Way, Suite 200
Portage, Michigan 49002

Re: K171152
Trade/Device Name: Stryker Universal Neuro III System AXS Screw
Regulation Number: 21 CFR 882.5360
Regulation Name: Cranioplasty Plate Fastener
Regulatory Class: Class II
Product Code: HBW
Dated: April 19, 2017
Received: April 20, 2017

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,

Michael J. Hoffmann -S

for 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)*
K171152

Device Name
Stryker Universal Neuro III System AXS Screw

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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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 Staff Regulatory Affairs Specialist Stryker Craniomaxillofacial 750 Trade Centre Way Portage, MI 49002 Phone: 269-389-5596 Fax: 877-648-7114
Date prepared:	May 12, 2017

II. DEVICE

Trade Name:	Stryker Universal Neuro III System AXS screw
Common or Usual name:	Cranioplasty plate fastener
Classification name:	Cranioplasty Plate Fastener 21 CFR §882.5360
Regulatory Class:	Class II
Product Code:	HBW

III. PREDICATE DEVICE

Predicate: Stryker Universal Neuro III System AXS Screw – K151387
Reference Devices: K120352 Stryker QuikFlap Sterile Procedure Pack, and K131775 Universal Neuro 3 System

IV. DEVICE DESCRIPTION

The Stryker Universal Neuro III System (UN III) consists of an assortment of different bone plates and screws. The predicate device, the UN III AXS screw, is a part of the overall UN III System, and was cleared in K151387. Here, this special 510(k) is submitted to show the ability to market the UN III AXS screw sterile in two different sterile packaging configurations which are:

1. UN III AXS Screws packed in sterile procedure packs, and
2. UN III AXS Screws packed in a sterile screw cartridge.

The specific devices included are:

Description	Packaging Configuration Type
2-Hole Plate Set, SD Screw	UN III AXS Sterile Procedure Pack
2-Hole Plate Set, ST Screw	UN III AXS Sterile Procedure Pack
2-Hole Plate Set, Low Profile with Tab	UN III AXS Sterile Procedure Pack
2-Hole Plate / Burr Hole Cover 14mm Set	UN III AXS Sterile Procedure Pack
2-Hole Plate / Burr Hole Cover 20mm Set	UN III AXS Sterile Procedure Pack
Burr Hole Cover 14mm Set	UN III AXS Sterile Procedure Pack
UN III AXS Screw, ST, 1.5x4mm	UN III AXS Sterile Screw Cartridge
UN III AXS Screw, ST, 1.5x5mm	UN III AXS Sterile Screw Cartridge
UN III AXS Screw, ST, 1.5x6mm	UN III AXS Sterile Screw Cartridge
UN III AXS Screw, SD, 1.5x3mm	UN III AXS Sterile Screw Cartridge
UN III AXS Screw, SD, 1.5x4mm	UN III AXS Sterile Screw Cartridge
UN III AXS Screw, SD, 1.5x5mm	UN III AXS Sterile Screw Cartridge
UN III AXS Screw, Emergency, 1.7x4mm	UN III AXS Sterile Screw Cartridge

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).

Offering the AXS screw sterile does not alter the Indications for Use statement for the proposed device. The Indications for Use is identical to the predicate device from the Stryker Universal Neuro III System (K151387).

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject device 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 UN III AXS screw is unchanged from the predicate and remains the same.

B. Technological Characteristics

The technological characteristics remain the same as the predicate and are unchanged.

VII. PERFORMANCE DATA

In Table 5.1 below, the relevant topics, as given in ”Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile Guidance for Industry and Food and Drug Administration Staff (2016),” are referenced.

Table 5-1: Reference of testing

Category A Sterilization Methods – Established Method	Gamma Radiation
Sterilization Chamber:	Terminally sterilized in final packaging.
SAL	SAL 1 x 10^{-6} for all products
Pyrogenicity	Acceptance Criteria met
Packaging Description	Sterile Barrier Systems: Procedure Packs: Flexible bag (sealed) Screws: Blister (sealed)

Process Validations

Overall the subject device is unchanged and has the same implant material and manufacturing process, and the same duration or location of contact to the patient as the predicate device. The only difference between subject device and predicate device lies in the sterile packaging process required with the two sterile barrier systems referenced above.

To evaluate the influence of the changes compared to the predicate device, and based on the Risk Analysis performed on the modification of providing the UN III AXS screw sterile, the following validations were performed and referenced in support of substantial equivalence:

- Process Cleaning Validation (Bioburden level, Process residuals, Endotoxin Level)
- Sealing Validation of seals closing the sterile barrier systems
- Process Sterilization Validation Gamma Radiation with $VD_{max}25$ Cycle

A Biocompatibility Assessment was performed to support substantial equivalence respecting the additional manufacturing process steps due to the sterile packaging compared to the predicate device. Substantial equivalence was proven.

Performance Bench Testing

The following performance bench tests were completed and referenced.

- Transport safety of product and sterile barrier system including weight and compression test
- Shelf life and integrity of sterile barrier system
- Handling test of overall packaging functionality

The subject device met all pre-defined acceptance criteria. Overall, the results of the performance bench tests support the substantial equivalence of the subject device to the predicate 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 AXS sterile screws 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.