November 13, 2017

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

Re: K170725
Trade/Device Name: Stryker Universal Mesh
Regulation Number: 21 CFR 882.5320
Regulation Name: Preformed Alterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: GWO
Dated: October 10, 2017
Received: October 11, 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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)*
K170725

Device Name
Stryker Universal Mesh

Indications for Use *(Describe)*
The Universal Mesh is indicated for reconstruction, stabilization and/or rigid fixation subsequent to craniotomy, craniectomy, cranioplasty, 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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510(k) Summary

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

I. SUBMITTER [§807.92(a)(1)]

510(k) Owner:	Stryker Leibinger GmbH & Co. KG Boetzinger Strasse 41 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:	November 6, 2017

II. DEVICE [§807.92(a)(2)]

Trade Name:	Stryker Universal Mesh
Common or Usual name:	Bone Plate
Classification name:	Preformed Alterable Cranioplasty Plate
Regulatory Class:	Class II
Product Code:	GWO

III. PREDICATE DEVICE [§807.92(a)(3)]

Universal Mesh System – K161821

IV. DEVICE DESCRIPTION [§807.92(a)(4)]

The 3D Preformed meshes are added to the Universal Mesh system in order to offer a more comprehensive selection of mesh solutions for cranial reconstruction. Simply put, the 3D Preformed meshes are the 1.5/1.7mm Dynamic Mesh predicate design provided in a

preformed shape. The 3D Preformed meshes are provided non-sterile in 2 different variations; these meshes are offered in a Symmetrical Preformed mesh and an Anatomically preformed lateral mesh. The Anatomically preformed lateral 3D meshes add a 1.0mm thick mesh option to the portfolio, which was not available with the predicate device.

V. INDICATIONS FOR USE [§807.92(a)(5)]

TABLE 1: COMPARISON OF INDICATIONS FOR USE

	Subject Device	Predicate – K161821
Indications for Use	The Universal Mesh is indicated for reconstruction, stabilization and/or rigid fixation subsequent to craniotomy, craniectomy, cranioplasty, and cranial fractures in adults and adolescents (age 12 and higher).	The Universal Mesh is indicated for reconstruction, stabilization and/or rigid fixation subsequent to craniotomy, craniectomy, cranioplasty, and cranial fractures in adults and adolescents (age 12 and higher).

The predicate device is indicated for use in the cranial skeleton. The Indications for Use statement of the subject Universal 3D Preformed Mesh is unchanged and remains identical to the predicate device.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE [§807.92(a)(6)]

The Stryker Universal Mesh is compared to its predicate devices for substantial equivalence based on the following criteria:

A. Principle of Operation
B. Technological Characteristics

A. Principle of Operation

The Stryker Universal 3D Preformed Mesh implants are designed for the reconstruction, stabilization and rigid fixation of the bony areas of the cranial skeleton. The necessary instrumentation are included with the system.

The Principle of Operation of the subject Universal 3D Preformed Mesh is unchanged and remains identical to the predicate device.

B. Technological and Operational Characteristics

At a high level, the Subject devices and Predicate devices are based on the following technological elements:

- Same materials: Both the subject device and predicate device are made of titanium according to ASTM F67
- Same mode of fixation: implant fixation with screws
- Same mesh pattern: The Subject device has the same Dynamic Mesh pattern as the predicate device, however is provided in 1.0mm thickness.
- Similar Design/Sizes: The Subject device 3D Preformed mesh is designed to offer the surgeon a pre-bent version of an existing mesh, to minimize the time the surgeon needs for bending the implant into the desired shape. The 3D Preformed mesh are designed to be modified by the surgeon as needed to fit the patient needs, the same as the predicate mesh.

VII. PERFORMANCE DATA [§807.92(b)(1)]

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

The biocompatibility evaluation for the subject device was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "*Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'*" May 1, 1995, and International Standard ISO 10993-1 "*Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process*," as recognized by FDA. The tests supported the biocompatibility of the device.

The implant is made from titanium which conforms to ASTM F67 for chemical composition, which is the same as the predicate. Cytotoxicity testing was performed using DIN EN 10993-5:2009, *Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity*. The tests supported the biocompatibility of the device.

Performance Bench Testing

The following performance bench tests were completed.

Test	Test Method Summary	Results
Sterilization Validation	Validate the sterilization instructions for the Subject device according to internal standard. Referenced standards: ISO 14937, ISO 17664, ISO 17665 – 1&2, AAMI TIR 12, AAMI ST 81, AAMI ST79.	Method validated.
Static Load Max. Defect	Determination of defined load and deformation over maximum defect according to labeling of fixated meshes with bone simulation material	Acceptance criterion were met, tests were passed.

Static Load	Determination of defined load and deformation over 70mm diameter defect according to labeling of fixated meshes with bone simulation material. Comparison to predicate device tested over same defect.	Acceptance criterion were met, tests were passed.
End User Validation Testing	Surgeon evaluation	Acceptance criterion was met, test was passed
Internal Handling Test	Non-trained user evaluation	Acceptance criterion was met, test was passed
MR Compatibility	Magnetic Resonance (MR) testing was performed on the subject device mesh implants in accordance with FDA guidance for industry "Assessment of Radiofrequency – Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices,"March 22, 2016. MR heat testing has been performed on the Subject device according to FDA final guidance "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment," December 11, 2014.	Based on the results of these evaluations, the Stryker Universal mesh will be labeled as MR conditional.

The Subject device met all pre-defined acceptance criteria and standards and was found to not represent a new worst case. Overall, the results of the performance bench tests support the substantial equivalence of the Subject device to the predicate.

Animal Testing

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

Clinical Testing [§807.92(b)(2)]

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

VIII. CONCLUSIONS [§807.92(b)(3)]

The results of the non-clinical data demonstrate the Stryker Universal 3D Preformed Mesh will perform as intended in the specified use conditions. According to the comparison based on the requirements of 21 CFR 807.92 and the information provided herein, it is concluded that the information included in this submission supports substantial equivalence.