November 6, 2018

Stryker Leibinger GmbH & Co. KG
Gregory Gohl
Sr. Regulatory Affairs Specialist
Boetzinger Strasse 41
Freiburg, D-79111 De

Re: K182425
Trade/Device Name: Universal Mesh - Sterile
Regulation Number: 21 CFR 882.5320
Regulation Name: Preformed Alterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: GWO, JEY
Dated: September 5, 2018
Received: September 6, 2018

Dear Gregory Gohl:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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.

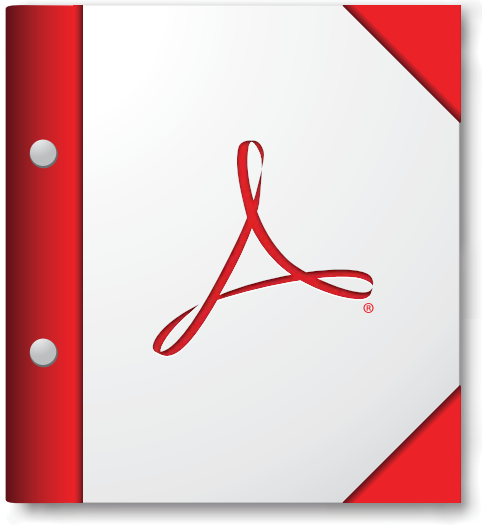
For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, 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,

Matthew C. Krueger -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



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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

510(k) Owner:	Stryker Leibinger GmbH& Co. KG Boetzinger Strasse 41 D-79111 Freiburg, Germany
Submitter/ Contact Person:	Gregory Gohl Sr. Regulatory Affairs Specialist Stryker Craniomaxillofacial (CMF) 750 Trade Centre Way Portage, MI 49002 Phone: 269-389-4319 Fax: 877-648-7114
Date prepared:	September 5, 2018

II. DEVICE [§807.92(a)(2)]

A. Neuro Branch Submission Device

Trade Name:	Universal Mesh - Sterile
Common or Usual name:	Bone Plate
Classification Name:	Preformed alterable cranioplasty plate 21 CFR 882.5320
Regulatory Class:	Class II
Product Code:	GWO

B. Dental Branch Submission Device

Trade Name:	Universal Mesh - Sterile
Common or Usual name:	Bone Plate
Classification Name:	Bone Plate; 21 CFR 872.4760
Regulatory Class:	Class II
Product Code:	JEY

*Note the company Stryker or legacy name Stryker Leibinger precedes the product/trade name and predicate device in some documentation.

III. PREDICATE DEVICE [§807.92(a)(3)]

A. Neuro Branch Submission Device

Stryker Universal Mesh – K161821

B. Dental Branch Submission Device

Stryker Universal Mesh – K170773

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

A. Neuro Branch Submission Device

The Universal Mesh – Sterile consists of an assortment of titanium meshes with different dimensions (small 60x60, medium 90x90, and large 120x120 mm) within the framework of the predicate Stryker Universal Mesh.

The design of the meshes is not changed. The only addition is to provide the meshes sterile in a suitable packaging system. These meshes are sterilized by exposure to Ethylene Oxide. The intended use, the principles of operation, and the materials of construction have not changed.

B. Dental Branch Submission Device

The Universal Mesh – Sterile consists of an assortment of titanium meshes with different dimensions (small 60x60, medium 90x90, and large 120x120 mm) within the framework of the predicate Stryker Universal Mesh.

The design of the meshes is not changed. The only addition is to provide the meshes sterile in a suitable packaging system. These meshes are sterilized by exposure to Ethylene Oxide. The intended use, the principles of operation, and the materials of construction have not changed.

V. INDICATIONS FOR USE

A. Neuro Branch Submission Device

TABLE 5-1: COMPARISON OF INDICATIONS FOR USE

	Subject Device	Predicate Device – 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).

B. Dental Branch Submission Device

TABLE 5-2: COMPARISON OF INDICATIONS FOR USE

	Subject Device	Predicate – K170773
Indications for Use	The Universal Mesh is indicated for non-load-bearing reconstruction in the maxillofacial skeleton of patients in whom skeletal growth is complete.	The Universal Mesh is indicated for non-load-bearing reconstruction in the maxillofacial skeleton of patients in whom skeletal growth is complete.

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. Principles of Operation
B. Technological Characteristics

A. Principles of Operation / Operating Principle

The basic operational principle of the Universal Mesh – Cranial (K161821) and the secondary predicate device Universal Mesh- Dental (K170773) remains the same: the Stryker Universal Meshes are designed to aid in the reconstruction and stabilization (plus rigid fixation for the Neuro submission) of the bony areas of the cranial skeleton. The mesh can be modified by cutting and bending instruments for anatomical adaptation. The necessary instrumentation and related product storage are provided by the Stryker Universal Meshes.

B. Technological Characteristics

The fundamental scientific technology of the Universal Mesh - Sterile has not changed. This is because the design of the meshes has not changed. The only addition is to provide the meshes sterile in a suitable packaging system for sterile delivery. The intended use and principles of operation, as well as, materials of construction and operational characteristics have not changed.

- Intended Use: Same.
- Materials of Construction: The subject meshes are manufactured out of the same material as the predicate device.
- Mechanism of Action: Same.
- Mode of Fixation: Same.
- Packaging: The subject device is delivered sterile while the predicate device is dispensed non-sterile.

Overall, the change does not alter the subject device significantly and does not represent a new worst case in design.

VII. PERFORMANCE DATA

Based on the Risk Analysis performed on the modifications to the Stryker Universal Mesh, bench testing was performed in support of the substantial equivalence determination.

There is no change in the design, material, manufacturing process, or duration/location of contact. The only change is to provide the meshes sterile by Ethylene Oxide sterilization. The performed tests were therefore designed to prove that the chosen packaging is suitable to encompass the meshes and maintain sterility. The performance of the sterilization cycle at Steris was evaluated, as well.

Performance Bench Testing

The following performance bench tests were completed.

Characteristic	Test	Result
Biocompatibitily	EtO Residuals Test	Passed
Biocompatibitily	Cytotoxicity	Passed
Biocompatibitily	Endotoxin Testing	Passed
Biocompatibitily	Sterilization Validation	Passed
Biocompatibitily	Bioburden verification	Passed
Packaging Performance	Transportation Test	Passed
User Validation	System Handling Test	Passed

The subject device met all pre-defined acceptance criteria and standards. The subject device was not found to represent a new worst-case. 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 Stryker Universal Mesh resulting in Universal Mesh - Sterile will perform as intended in the specified use conditions. The intended use, principles of operation, and fundamental scientific technology of the Universal Mesh - Sterile has not changed compared to the predicate device. This is because the design of the meshes has not changed. The only addition is to provide the meshes sterile in a suitable packaging system. 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.