August 15, 2019

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

Re: K191916
Trade/Device Name: Stryker CMF MEDPOR Priority Customized Implant Kit
Regulation Number: 21 CFR 878.3550
Regulation Name: Chin Prosthesis
Regulatory Class: Class II
Product Code: FWP
Dated: July 16, 2019
Received: July 17, 2019

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Nina Mezu-Nwaba, PharmD., MPH., MSc,
CAPT., United States Public Health Service
Assistant Director (Acting), Plastic Surgery Implant Devices Team
Division of Infection Control and Plastic Surgery Devices
Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191916

Device Name
Stryker CMF MEDPOR Priority Customized Implant Kit

Indications for Use *(Describe)*
The Stryker CMF MEDPOR Customized Implant is indicated for the augmentation and/or restoration of bony and/or soft tissue deformities in post-traumatic, post-surgical, or congenital craniofacial defects, including, but not limited to, the correction and prevention of persistent temporal hollowing (PTH).

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.

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

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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 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:	July 16, 2019

II. DEVICE [§807.92(a)(2)]

Trade Name:	Stryker CMF MEDPOR Priority Customized Implant Kit
Abbreviated Name:	MEDPOR Priority CI Kit
Common or Usual Name:	Customized Implant
Device:	Prosthesis, Chin, Internal; per 21 CFR §878.3550
Classification Name & Regulation Description:	Chin prosthesis; per 21 CFR §878.3550
Regulation Medical Specialty & Review Panel:	General & Plastic Surgery
Product Code:	FWP
Regulatory Device Class:	Class II

*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)]

510(k) Number: K191916

Predicate Device: Stryker CMF MEDPOR Customized Implant (also referred to as MEDPOR CIs or MEDPOR CI Kits) - K153508

Reference Device: PEEK Customized Cranial Implant (CCI) Priority - K152076

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

The Stryker CMF MEDPOR Customized Implant, also referred to as MEDPOR CIs, product offerings provide customized cranial or craniofacial patient specific implants based on CT data and surgeon input. These MEDPOR CIs are currently packaged into MEDPOR CI Kits with a patient-specific Host Bone Model (HBM) that represents the 3D patient's anatomy surrounding the defect location. This Special 510(k) is submitted specifically to include the customer option to sell new Stryker CMF MEDPOR Priority Customized Implant Kits without the Host Bone Model subcomponent.

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

TABLE 5-1: COMPARISON OF INDICATIONS FOR USE

	Subject Device	Predicate Device – K153508
Indications for Use	The Stryker CMF MEDPOR Customized Implant is indicated for the augmentation and/or restoration of bony and/or soft tissue deformities in post-traumatic, post-surgical, or congenital craniofacial defects, including, but not limited to, the correction and prevention of persistent temporal hollowing (PTH).	The Stryker CMF MEDPOR Customized Implant is indicated for the augmentation and/or restoration of bony and/or soft tissue deformities in post-traumatic, post-surgical, or congenital craniofacial defects, including, but not limited to, the correction and prevention of persistent temporal hollowing (PTH).

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

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 Stryker CMF MEDPOR Customized Implant remains the same as the predicate: The MEDPOR CIs are intended to be used to fill bony voids, defects, and contour irregularities in non-load bearing regions of the craniofacial skeleton.

B. Technological Characteristics

The technological characteristics remain the same as the predicate:

- Same Intended Use: The Stryker CMF MEDPOR Customized Implant is indicated for the augmentation and/or restoration of bony and/or soft tissue deformities in post-traumatic, post-surgical, or congenital craniofacial defects, including, but not limited to, the correction and prevention of persistent temporal hollowing (PTH).
- Same Operating Principle: to fill bony voids, defects, and contour irregularities in non-load bearing regions of the cranial skeleton.
- Same Mode of Fixation: fixated to the native bone with Stryker Neuro, Midface, and/or Upperface self-drilling screws.
- Same Materials of Construction: Implants are made from high density polyethylene (HDPE).
- Same Design: the customized craniofacial implants are molded from HDPE to the specific reconstruction boundaries indicated by the surgeon via submission of CT scans and a customized implant request.

VII. PERFORMANCE DATA [§807.92(b)(7)]

The modifications described in this submission is the optional removal of the Host Bone Model subcomponent from the Stryker CMF MEDPOR Customized Implant Kit. This introduces a new product offering called the Stryker CMF MEDPOR Priority Customized Implant Kit, also referred to as the MEDPOR Priority CI Kit. There are no changes to the MEDPOR CI device itself.

Without the Host Bone Model in the MEDPOR Priority CI Kit, the necessity to gamma sterilize a subcomponent no longer exists. Therefore, Stryker Sustainability Solutions (SSS)

Incorporated was identified and evaluated as an additional Ethylene Oxide (EO) sterilization location for MEDPOR CIs due to the location's ability to achieve a quicker turnaround time to the end-user. SSS was proven to be as safe and effective for sterilization as the predicate location (see Section 14 for sterilization evaluation and adoption).

A risk analysis was performed, and sterilization 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 necessary to evaluate by testing is the additional sterilization location for MEDPOR CIs. The tests were performed to adopt the MEDPOR Priority CI Kit into existing Cycle 51 at Stryker Sustainability Solutions.

Sterilization and Biocompatibility Testing

Characteristic	Test	Result
Sterilization	Product Adoption	Passed
Sterilization / Biocompatibility	EO Residual	Passed

Performance Bench Testing

Performance bench testing was not required as a basis for substantial equivalence.

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)]

In summary, the Stryker CMF MEDPOR Priority Customized Implant Kit is substantially equivalent to its predicate device. The fundamental scientific technology has not changed from the predicate device since the design of the Stryker CMF Customized Implant subcomponent has not changed. The only addition is to provide a MEDPOR Priority CI Kit with two identical sterile implants and no Host Bone Model in a suitable packaging system. The intended use, technological characteristics, and materials of construction have not changed as discussed in detail above and other sections of the submission. The modifications do not raise new questions of safety or effectiveness. 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.