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

March 23, 2015

Stryker Leibinger
Ms. Julie Schoell
Staff Regulatory Affairs Specialist
750 Trade Centre Way, Suite 200
Portage, Michigan 49002

Re: K143173
Trade/Device Name: Stryker CMF MEDPOR® Customized Implant
Regulation Number: 21 CFR 878.3550
Regulation Name: Chin prosthesis
Regulatory Class: Class II
Product Code: FWP
Dated: February 17, 2015
Received: February 18, 2015

Dear Ms. Schoell:

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" (21CFR 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,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*

K143173

Device Name
Stryker CMF MEDPOR® Customized Implant

Indications for Use *(Describe)*
The Stryker CMF MEDPOR® Customized Implant is intended for the augmentation or restoration of bony contour in craniofacial defects.

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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510(k) SUMMARY (Per 21 CFR 807.92)

I. SUBMITTER

510(k) Owner:	Stryker Leibinger GmbH& Co. KG Boetzinger Strasse 41 D-79111 Freiburg, Germany
Submitter/ Contact Person:	Julie Schoell Staff Regulatory Affairs Specialist Stryker Craniomaxillofacial 750 Trade Centre Way Portage, MI 49002 Phone: 269-389-3419 Fax: 877-648-7114
Date prepared:	November 3, 2014

II. DEVICE

510(k) Number:	K143173
Trade Name:	Stryker CMF MEDPOR® Customized Implant
Common name:	Prosthesis, chin, internal
Classification name:	Chin prosthesis (21 CFR 878.3550)
Regulatory Class:	Class II
Product Code:	FWP

III. PREDICATE DEVICE

Stryker CMF MEDPOR Customized Implant – K121315
This predicate has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The Stryker CMF MEDPOR® Customized Implant is sold as a kit of two identical implants plus one host bone model. The Stryker CMF MEDPOR Customized Implants are molded from porous high density polyethylene (HDPE) to the specific reconstruction boundaries indicated by the surgeon via submission of CT scans and a customized implant request. The porous structure of the MEDPOR material allows for tissue ingrowth. The implant is fixed into place using compatible Stryker fixation systems. The implants and host bone model are provided sterile for single use only.

Proposed Modification: The Subject device Stryker CMF MEDPOR Customized Implant has the same Intended Use/Indications for use, material, and operational principle as the Primary predicate Stryker CMF MEDPOR Customized Implant K121315. This 510(k) is being submitted to allow for two additional surgeon design options.

V. INDICATIONS FOR USE

The Stryker CMF MEDPOR Customized Implant is intended for the augmentation or restoration of bony contour in craniofacial defects.

The proposed modifications do not alter the Intended Use/Indications for Use statement for the Subject device. The Intended Use/Indications for Use is identical to the Primary predicate device Stryker CMF MEDPOR Customized Implant K121315.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Stryker CMF MEDPOR Customized Implant is compared to its predicate device for substantial equivalence based on the following criteria:

A. Principle of Operation
B. Technological Characteristics

A. Principle of Operation

The basic operational principle of the Stryker CMF MEDPOR Customized implant remains the same: to augment or restore bony contours in the craniofacial region. The Subject device allows for fixation with previously cleared Stryker screws with the addition of plates from the same previously cleared Stryker product line. Both the Subject device and the Predicate device can be trimmed and contoured to fit the specific needs of the patient. The Subject device and the Predicate device are permanent implants and have the same craniofacial area of application.

B. Technological and Operational Characteristics

The Subject device and Predicate devices are based on the following technological elements:

- Same operating principle: to augment or restore bony contours in the craniofacial region
- Same area of contact and contact duration (tissue/bone/greater than 30 days)
- Same sizes as the Primary predicate device
- Same material: there is no change in the implant or host bone material
- Same sterilization method: there is no change in the implant or host bone sterilization method

- Similar design process: the proposed modification allows for additional design options compared to the Primary predicate. The surgeon may now choose a non-flanged inlay implant and provide additional "single stage" design inputs for the scope of the implant reconstruction boundary.
- Similar mode of fixation: screw fixation with the addition of plate fixation

VII. PERFORMANCE DATA

Based on the Risk Analysis performed on the modifications to the device, the following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing
Biocompatibility testing was not required as a basis for substantial equivalence. There is no change in the material, duration or location of contact or sterilization method.

Performance Bench Testing
The following performance bench tests were completed.

- Screw Pullout Testing
- End user validation testing

Software Verification and Validation Testing
The Stryker CMF MEDPOR Customized Implant does not directly contain software or have an electronic user interface.

Software is used in the design process of the Stryker CMF MEDPOR Customized Implant. The addition of the single stage design option does not change the manufacturing process. The same internal control systems as cleared in the predicate K121315 remain unchanged.

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 the Stryker CMF MEDPOR Customized Implant 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.