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 10, 2016

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

Re: K153248
Trade/Device Name: Stryker PEEK Customized Cranial Implant Kit
Regulation Number: 21 CFR 882.5320
Regulation Name: Preformed Alterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: GWO
Dated: February 8, 2016
Received: February 9, 2016

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 yours,

William J. Heetderks -A

Digitally signed by William J. Heetderks -A
DN: c=US, o=U.S. Government, ou=HHS, ou=NIH, ou=People, 0.9.2342.19200300.100.1.1=0010149848, cn=William J. Heetderks -A
Date: 2016.03.10 19:25:38 -05'00'

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)*
K153248

Device Name
Stryker PEEK Customized Cranial Implant Kit

Indications for Use *(Describe)*
The PEEK Customized Cranial Implant Kit is indicated for the augmentation and/or restoration of bony and/or soft tissue deformities in the cranial and craniofacial skeleton (orbital rim, zygoma, and adjacent bone); including but not limited to, the correction and prevention of persistent temporal hollowing (PTH) in patients 12 years of age and older.

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

510(k) Owner:	Stryker Leibinger GmbH& Co. KG Boetzinger Strasse 41 D-79111 Freiburg, Germany
Submitter/ Contact Person:	Jonathan Schell Sr. Regulatory Affairs Specialist Stryker Craniomaxillofacial 750 Trade Centre Way Portage, MI 49002 Phone: 269-389-5596 Fax: 877-648-7114
Date prepared:	November 6, 2015

II. DEVICE

Trade Name:	Stryker PEEK Customized Cranial Implant Kit
Common or Usual name:	Customized Cranial Implant
Classification name:	Preformed alterable cranioplasty plate 21 CFR §882.5320
Regulatory Class:	Class II
Product Code:	GWO

III. PREDICATE DEVICE

Predicate: Stryker PEEK Customized Cranial Implant Kit – K121153

This predicate has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The Stryker PEEK Customized Cranial Implant (CCI) product offerings provide customized cranial or craniofacial (craniofacial region is defined as the orbital rim, zygoma, and adjacent bone) patient specific implants based on CT data and surgeon input. This traditional 510(k) is submitted to add an additional indication for use to augment and/or restore soft tissue deformities in the cranial and craniofacial skeleton; including but not limited to, the correction and prevention of persistent temporal hollowing (PTH).

V. INDICATIONS FOR USE

The PEEK Customized Cranial Implant Kit is indicated for the augmentation and/or restoration of bony and/or soft tissue deformities in the cranial and craniofacial skeleton (orbital rim, zygoma, and adjacent bone); including but not limited to, the correction and prevention of persistent temporal hollowing (PTH) in patients 12 years of age and older.

The Indications for Use statement of the PEEK CCI with the PLUS design is different than the predicate device, but this difference does not constitute a new Intended Use. Both the PEEK CCI with the PLUS design and the predicate device have the same Intended Use to fill bony voids, defects, and contour irregularities in non-load bearing regions of the cranial skeleton. Also, this difference does not alter the intended therapeutic use of the device nor does the difference affect the safety and effectiveness of the device relative to the predicate device.

A literature review was performed to identify relevant clinical literature with applicable data to show that, when compared to the predicate device, the new Indication for use added to the subject device does not raise new questions of safety or effectiveness. The results of this review provides evidence of this fact.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The PEEK CCI with the PLUS design 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 PEEK CCI with the PLUS design remains the same as the predicate: the PEEK Customized Cranial Implant is intended to be used to fill bony voids, defects, and contour irregularities in non-load bearing regions of the cranial skeleton.

B. Technological and Operational Characteristics

The addition of a new indication for use to the PEEK CCI does not alter the technological characteristics of the actual customized cranial or craniofacial implant. The technological characteristics remain the same as the predicate:

- 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-tapping screws. The Stryker Neuro, Midface, and, or, Upperface standard drill bits are used to drill the pilot hole.
- Same material: Implants are made of medical grade PEEK Optima LT1. Both predicate and subject devices are milled out of a block using industrial milling machines.
- Same design: Provides a "drop-in-fit" without a need for intra-operative modifications. If minor intra-operative size reduction is required, the implant can be trimmed with standard surgical burrs by the surgeon.

VII. PERFORMANCE DATA

Biocompatibility Testing

Biocompatibility and sterility testing of the device is not required as a basis for substantial equivalence. There is no change in the material, duration or location of contact, or reprocessing methods for the PEEK CCI. The same manufacturing processes and identical materials are used in the predicate device and the Subject device.

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

To support the inclusion of the PLUS design option, and the corresponding indication for use, Stryker has leveraged clinical literature and case history. A summary of the clinical literature verifies that PTH reflects a deficiency in the bulk of the temporalis muscle or overlying temporal fat pad. Surgical results with augmented implant designs have been published upon and shown to be clinically successful in addressing PTH.

To that end, Stryker has incorporated surgeon design input into a customized implant with an augmented contour. In all patient-specific reconstructions, the level of implant augmentation may be adjusted based on surgeon clinical knowledge of the patient condition and the

surgical approach. This culmination of surgeon input and approval and case history results in the CCI PLUS, which has shown that the augmented contour of the CCI PLUS potentially counteracts the asymmetry observed in PTH cases.

VIII. CONCLUSIONS

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.