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

August 26, 2015

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

Re: K152076
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: July 24, 2015
Received: July 27, 2015

Dear Mr. Jonathan 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,

Carlos L. Pena -S

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)*
K152076

Device Name
Stryker PEEK Customized Cranial Implant Kit

Indications for Use *(Describe)*

The Stryker PEEK Customized Cranial Implant Kit is intended to be used to replace bony voids in the cranial and the craniofacial skeleton.

The Stryker PEEK Customized Cranial Implant Kit is indicated for filling bony voids in the cranial and craniofacial skeleton 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.

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

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:	July 24, 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) is intended to replace bony voids in the cranial and the craniofacial skeleton in patients 12 years of age and older. The PEEK CCI product offerings provide customized cranial or craniofacial patient specific implants based on CT data and surgeon input. This special 510(k) is being submitted due to the optional removal of the Host Bone Model from the PEEK CCI Kit which creates the PEEK Customized Cranial Priority Implant product offering, and also the standard PEEK Customized Cranial Implant product offering.

INDICATIONS FOR USE

The Stryker PEEK Customized Cranial Implant Kit is intended to be used to replace bony voids in the cranial and the craniofacial skeleton.

The Stryker PEEK Customized Cranial Implant Kit is indicated for filling bony voids in the cranial and craniofacial skeleton in patients 12 years of age and older.

The proposed modifications do not alter the Indications for Use statement for the proposed device. The Indications for Use is identical to the predicate device Stryker PEEK Customized Cranial Implant Kit (K121153).

V. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The modified PEEK CCI Kit is compared to its predicate device for substantial equivalence of technological characteristics based on the following criteria:

A. Principle of Operation
B. Technological Characteristics

A. Principle of Operation

The basic operational principle of the modified PEEK CCI Kit remains the same as the predicate: the operating principle for the PEEK CCI is to fill bony voids in the cranial and craniofacial skeleton. The method of site preparation and fixation remains unchanged.

B. Technological Characteristics

Making the Host Bone Model optional, and the addition of two new product offerings to the PEEK CCI Kit does not alter the technological characteristics of the actual customized cranial or craniofacial implant. The technological characteristics remain the same:

- Same operating principle: to fill bony voids in the cranial and craniofacial 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.

VI. PERFORMANCE DATA

The modification described in this submission is the optional removal of the Host Bone Model from the PEEK CCI Kit, which creates additional product offerings. There are no proposed changes to the device itself. A risk analysis was performed and the results confirmed that no new performance tests were needed for the modified product offerings.

Biocompatibility and sterility testing of the new product offerings was not required as a basis for substantial equivalence. There is no change in the material, duration or location of contact, or reprocessing methods.

Performance Bench Testing

Performance bench testing was not required as a basis for substantial equivalence as evaluated by the performed risk analysis.

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.

VII. 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.