February 9, 2021

Stryker
Zainab Amini
Senior Regulatory Affairs Specialist
750 Trade Centre Way - Suite 200
Portage, Michigan 49002

Re: K203055
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: December 10, 2020
Received: December 11, 2020

Dear Zainab Amini:

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,

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine 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)*
K203055

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 3.5 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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/ Author/Contact Person:	Zainab Amini Senior Regulatory Affairs Specialist Stryker Craniomaxillofacial 750 Trade Centre Way Portage, MI 49002 Phone: 269-290-8072 Fax: 877-648-7114
Date prepared:	February 8, 2021

II. DEVICE

Trade Name:	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: K190229, Stryker PEEK Customized Cranial Implant Kit

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

IV. DEVICE DESCRIPTION

The PEEK Customized Cranial Implant Kit product provides a customized cranial or craniofacial patient specific implant solution based on patient CT/CBCT data and surgeon input. This submission is to expand the Stryker PEEK CCI product portfolio to include the single stage option.

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 3.5 years of age and older.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The PEEK Customized Cranial Implant Kit 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 principle of operation for the PEEK Customized Cranial Implant Kit is to fill bony voids, defects, and contour irregularities in non-load bearing regions of the cranial and craniofacial skeleton.

B. Technological and Operational Characteristics

Both the Subject and Predicate Devices have similar technological characteristics, and the principle of operation, mode of fixation, and design specification and manufacturing processes are all identical. Additionally, the subject device can be used in a single stage surgical procedure with or without marking guides or a navigation system to transfer the resection outline.

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 Customized Cranial Implant Kit. As the design and manufacturing processes, materials, and packaging processes are identical for both the predicate and the subject devices.

Performance Bench Testing

Both the subject and predicate devices are designed similarly and manufactured identically. The majority of the Performance Bench testing of the predicate device is valid for the subject device. Additionally, an end-user validation lab was conducted to evaluate the subject device and to support the basis for substantial equivalence. Table below provides a summary of the end-user validation.

Test	Test Methods Summary	Results
End-User Validation	• Single Stage surgical procedure with/&without the following surgical aid options: - Marking guides/guided; Virtual template/Navigation system; w/out surgical aid • Implant Fit	All V&V activities that were performed met their respective acceptance criteria. All end-user validation tasks were completed, passed successfully, and supports the substantial equivalence of the subject device to the predicate 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 evidence presented demonstrates that the subject device is as safe and effective as the legally marketed predicate and does not change nor raise any new questions of safety and effectiveness. In conclusion, in accordance to the requirement of 21 CFR 807.87, the PEEK Customized Cranial Implant Kit is substantially equivalent with respect to the safety and effectiveness to the legally marketed predicate device, K190229.