July 11, 2019

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

Re: K190229
Trade/Device Name: Stryker PEEK Customized Cranial Implant
Regulation Number: 21 CFR 882.5320
Regulation Name: Preformed Alterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: GWO
Dated: June 7, 2019
Received: June 10, 2019

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,

Matthew Krueger
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)*
K190229

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.

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Section 5. 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:	Zainab Amini Regulatory Affairs Specialist Stryker Craniomaxillofacial 750 Trade Centre Way Portage, MI 49002 Phone: 269-389-8349 Fax: 877-648-7114
Date prepared:	July 10, 2019

II. DEVICE

Trade Name:	Stryker PEEK Customized Cranial Implant
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: K153248, Stryker PEEK Customized Cranial Implant Kit

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 patient specific implants based on CT data and surgeon input.

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 CCI for Children 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 for Children is that the PEEK Customized Cranial Implant is intended 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 operating principle, mode of fixation, and design and manufacturing processes are all identical.

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. 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 and manufactured identically. As the Performance Bench testing of the Predicate Device are valid for the Subject Device, and because the performance bench testing of the both devices are identical, an additional performance bench testing was not required for the Subject Device as a basis for substantial equivalence.

Animal Testing

Animal testing was not required as a basis for substantial equivalence.

Clinical Testing

Clinical studies and findings show the potential benefits associated with the use of the device outweigh the potential risks associated with the Subject Device. Clinical studies provided within this submission indicates that the potential benefits for the patient will be greater from the use of the Subject Device when compared to the potential risks. The following table provides the scientific peer-reviewed publications describing the safe and effective application of alloplastic cranioplasties in patient 3.5 years of age and above.

TABLE 1 RELEVANT CLINICAL DATA

Source	Summary
Nguyen et al. 2018	Report on clinical outcomes following cranioplasty in children with patient-specific PEEK, titanium, and PMMA implants. Follow-up of an average of 30 months. Patient-specific implants provide significant degrees of freedom to the surgeon which bone grafting would not be able to accommodate because of lack of donor availability or sheer complexity of contouring. The authors did not find any indications that the implants pose a problem with the growing skeleton and suggested safety at ages greater than 3 years.
Rocque et al. 2018	Multicenter study at 13 institutions. Cranioplasty bone resorption is predicted by patient age. Reconstruction with PEEK implants is described in the study.
Ma et al. 2018	Cranioplasty with autologous bone in 84 cases, 36 split calvarial graft reconstructions, six PEEK implants, 33 titanium meshes. Average follow-up: 4 years. Good symmetry and effective brain protection were achieved.
Sainsbury et al. 2017	Bilateral malar reconstruction with customized PEEK implants based on CT data. The authors highlight the improved implant-bone surface interface with the customized medical devices.
Fu et al. 2016	Comparison of clinical outcomes achieved with autologous and alloplastic cranioplasty in pediatric patients. 73% of the included patients received alloplastic implants (PEEK, PMMA, MEDPOR, titanium) while the remaining 28% were treated with autologous reconstructions. Patients were followed-up for up to 9 years. The authors conclude that alloplastic cranioplasty in the pediatric population is a safe alternative, when autologous cranial bone is not available.

Potential Benefits

Potential benefits associated with the Subject Device outweigh the potential risks. Overall, the Subject Device implant offers similar benefits as the Predicate Device because the physical principle of replacing missing bone is identical. However, through investigation it was identified that the Subject Device's targeted age group would have many potential benefits that are of greater importance/magnitude for young patients.

Potential Risks

The potential risks associated with the device are increasing radiation exposure and growth issues. These risks have been assessed and mitigation is provided within this submission which reduces these potential risks for the patient.

TABLE 2 POTENTIAL RISKS IDENTIFIED FOR THE SUBJECT DEVICE:

	Potential Hazard	Potential Harm	Risk Mitigation in Labelling
Growth related risks	Brain compression against implant	Pain	IFU contains information regarding growth disturbance
		Removal of implant	
		Brain/soft tissue injury reversible	
		Brain/soft tissue injury irreversible	
	Implant interference with growing bone	Poor aesthetics resulting in implant removal	IFU contains information regarding growth disturbance
		Annoyance	
	Loosening of implant	Neurological symptoms requiring surgery	IFU contains information regarding growth disturbance
		Temporary neurological symptoms	
Radiation related risks	New / additional scan for implant design required	Radiation induced neoplasia	IFU and CT protocol contains information to reduce radiation dose

To mitigate the risks, the Instructions for Use (IFU) includes information associated with growth related risks. The IFU and the scan protocol include information to minimize ionizing radiation dose by using low-dose and child-size CT- protocols when appropriate.

CONCLUSIONS

The clinical studies provided within this submission, show the safe and effective use of the patient specific alloplastic implants for the intended patient population. Table 1 provides references and summary of these clinical studies.

A Benefit and Risk Factor analysis was conducted for the Subject Device. Both the potential benefits and risks of the Subject Device are increased when compared to the Predicate Device. However, the overall benefit and risk ratio remains equivalent. The product labeling contains corresponding information regarding the potential risks of growth disturbance and radiation exposure for the intended patient population. Table 2 provides an overview of the risk mitigation measures.

The safety and effectiveness of both the Subject and Predicate Devices are equivalent. Both devices are designed and manufactured identically, and they both have equivalent Intended Use and Technological Characteristics.

In conclusion, the potential benefits associated with the use of the Subject Device outweigh its potential risks for the patient. 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.

References

Fu, K. J., Barr, R. M., Kerr, M. L., Shah, M. N., Fletcher, S. A., Sandberg, D. I., … Greives, M. R. (2016). An outcomes comparison between autologous and alloplastic cranioplasty in the pediatric population. *Journal of Craniofacial Surgery*, *27*(3), 593–597. https://doi.org/10.1097/SCS.0000000000002491

Ma, I. T., Symon, M. R., Bristol, R. E., Beals, S. P., Joganic, E. F., Adelson, P. D., … Singh, D. J. (2018). Outcomes of Titanium Mesh Cranioplasty in Pediatric Patients. *The Journal of Craniofacial Surgery*, *29*(1), 99–104. https://doi.org/10.1097/SCS.0000000000004045

Nguyen, P. D., Khechoyan, D. Y., Phillips, J. H., & Forrest, C. R. (2018). Custom CAD/CAM implants for complex craniofacial reconstruction in children: Our experience based on 136 cases. *Journal of Plastic, Reconstructive and Aesthetic Surgery*, *18*(30251–1), 1–9. https://doi.org/10.1016/j.bjps.2018.07.016

Rocque, B. G., Agee, B. S., Thompson, E. M., Piedra, M., Baird, L. C., Selden, N. R., … Lam, S. K. (2018). Complications following pediatric cranioplasty after decompressive craniectomy: a multicenter retrospective study. *Journal of Neurosurgery: Pediatrics*, *22*(3), 225–232. https://doi.org/10.3171/2018.3.PEDS17234.

Sainsbury, D. C. G., George, A., Forrest, C. R., & Phillips, J. H. (2017). Bilateral Malar Reconstruction Using Patient-Specific Polyether Ether Ketone Implants in Treacher-Collins Syndrome Patients With Absent Zygomas. *The Journal of Craniofacial Surgery*, *28*(2), 515–517. https://doi.org/10.1097/SCS.0000000000003351