April 4, 2024

3D Systems, Inc.
Ashley Dawson
Director, Regulatory Affairs
5381 South Alkire Circle
Littleton, Colorado 80127

Re: K231834
Trade/Device Name: VSP PEEK Cranial Implant
Regulation Number: 21 CFR 882.5320
Regulation Name: Preformed Alterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: GWO
Dated: March 5, 2024
Received: March 5, 2024

Dear Ashley Dawson:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Digitally signed by Adam D. Pierce -S
Date: 2024.04.04 16:48:51 -04'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231834

Device Name
VSP PEEK Cranial Implant

Indications for Use *(Describe)*

The VSP PEEK Cranial Implant is indicated for use to fill a bony void or defect area in the cranial skeleton of patients 21 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: K231834

Applicant

Name: 3D Systems, Inc.

Address: 5381 South Alkire Circle
Littleton, CO 80127 USA
Phone: +1 (720) 643-1001

Official Contact: Ashley Dawson, PhD
Director, Regulatory Affairs, Healthcare

Date Prepared: April 3rd, 2024

Device

Trade Name: VSP PEEK Cranial Implant

Common Name: Cranial Implant

Classification Name: Preformed alterable cranioplasty plate

Classification: Class II, 21 CFR 882.5320

Product Code: GWO

Predicate Device

Predicate Device: Customized Craniofacial Implant (CCI) and Customized Skull Implant (CSI), Kelynium Global Inc. (K182711)

Device Description

The **VSP PEEK Cranial Implants** are non-load bearing, single use devices showing the following characteristics:

- The implants are designed individually for each patient to correct defects in cranial bone.
- The implants are 3D printed using material extrusion technology.
- The implants are manufactured using Polyetheretherketone (PEEK) implantable grade filament (i.e., Evonik VESTAKEEP® i4-3DF).

- The **VSP PEEK Cranial Implant**s are designed using CT imaging data and surgeon input.
- The implant size is ranging from 35 mm x 35 mm to 150 mm x 150 mm, and its thickness is constant, ranging from 3 mm to 6 mm with a nominal thickness of 3 mm.
- If minor intra-operative adjustments are required, the implants can be modified by the surgeon with standard surgical burrs.
- The implants are fixed to the native bone using commercially available cranial fixation screws and/or systems
- The implants are provided non-sterile for sterilization prior to implantation.

Indications for Use Statement

The **VSP PEEK Cranial Implant** is indicated for use to fill a bony void or defect area in the cranial skeleton of patients 21 years of age and older.

Predicate Comparison Table

The **VSP PEEK Cranial Implant** and its predicate device have the same functionality and similar technical data as shown in the table below.

	Subject Device VSP PEEK Cranial Implant	**Predicate Device Customized Craniofacial Implant (CCI) and Customized Skull Implant (CSI)**	**Remark**
Manufacturer	3D Systems, Inc.	Kelyniam Global Inc. (KGI)	
510K number	K231834	K182711	
Indications for Use	The VSP PEEK Cranial Implant is indicated for use to fill a bony void or defect area in the cranial skeleton of patients 21 years of age or older.	The Customized Craniofacial Implant (CCI) and Customized Skull Implant (CSI) is intended to fill a bony void or defect area in a patient's specific cranial and craniofacial skeleton (orbital rim, zygoma, & adjacent bone).	Indications of use for VSP PEEK Cranial Implant is equivalent to the predicate subject device Customized Skull Implant (CSI)
Material	Evonik VESTAKEEP® i4 3DF	Invibio Inc PEEK-Optima LT- 1® and Evonik Vestakeep i4®	Equivalent
Technical specifications	Plate - sized to each patient using CT scan data	Plate - sized to each patient using CT scan data	Same
Sterilization	Provided Non-sterile	Provided Non-sterile	Same

Product code	GWO (882.5320, Preformed Alterable Cranioplasty Plate)	GWO (882.5320, Preformed Alterable Cranioplasty Plate)	Same
Classification	Class II	Class II	Same

Brief Summary of Performance Testing

The impact of the differences in the manufacturing process on the device performances are studied in detail. The performance testing of the **VSP PEEK Cranial Implant** includes the following tests to evaluate the substantial equivalence of the subject device to the predicate device:

- Biocompatibility Testing
- Performance Bench Testing: Mechanics
- Performance Bench Testing: Anatomical fit

Biocompatibility Testing

The **VSP PEEK Cranial Implant** was biologically evaluated in order to verify compliance according to the technical specifications and standards of ISO-10993 ("Biological Evaluation of Medical Devices Part 1: Evaluation and Testing").

Biocompatibility tests were conducted according to the above-mentioned standards and the results obtained from test specimens were found to be within the acceptance criteria described in the standards.

Test	Results	Conclusion
Chemical Characterization and Toxicological Evaluation (ISO 10993-18 and ISO 10993-17)	Analysis of extractables by HS-GC-MS, GC-MS, LC-MS, and ICP-MS following exhaustive extraction	Acceptable Margin of Safety for all reported extractable substances
Cytotoxicity (ISO 10993-5)	Cell culture treated with test sample and compared dehydrogenase activity to control	Non-cytotoxic
Sensitization (ISO 10993-10)	In vivo Maximization Test	Non-sensitizing

Irritation (ISO 10993-23)	In vivo intracutaneous reactivity test	Non-irritating
Pyrogenicity (ISO 10993-11)	In vivo pyrogenicity test	Non-pyrogenic
Acute Systemic Toxicity (ISO 10993-11)	Clinical examination following injection in mouse model	Non-toxic
Implantation effects (ISO 10993-6)	Implantation within rat calvarial bone 28 day follow-up and 90 day follow-up	No unexpected results
Genotoxicity (ISO/TR 10993-33)	Reverse Mutation Assay	Non-Mutagenic
Genotoxicity (ISO/TR 10993-33)	In vitro Mammalian Cell Gene Mutation Assay	Non-Mutagenic

Performance Bench Testing

Various performance-bench tests regarding mechanics, including static testing and impact testing, were performed on the **VSP PEEK Cranial Implant**. The testing protocol was set up based on literature research, since there is no industry accepted standard governing mechanical testing for non-load bearing implantable prosthetic plates. Results indicate that the **VSP PEEK Cranial Implant** as replacements for bone defects have acceptable mechanical performance following sterilization or when used in combination with common osteosynthesis fixation systems.

Additionally, the size accuracy and usability of the implant was tested performing an anatomical fit test. Simulated surgical procedures were performed on anatomical models on test bench by surgeons. Several implantations were performed using commercially available cranioplasty fixation systems and reviewed by each surgeon. Results indicate that the size accuracy and usability of the **VSP PEEK Cranial Implant** is acceptable to surgeons.

The **VSP PEEK Cranial Implant** was bench tested in order to verify compliance according to the technical and biomechanical specifications.

Test	Test Method Summary	Results
Mechanical Performance Testing	Static compression testing and dynamic impact testing of extreme geometries (including screw fixation testing)	All samples passed the acceptance criteria
Anatomical Fit Testing	Size accuracy and usability surgeon questionnaire following implantation on anatomical model	The size accuracy and usability of the VSP PEEK Cranial Implant was acceptable to surgeons
Verification and Validation Testing	Technical and Biomechanical Specifications	All samples compliant with specifications.

CONCLUSION

According to the comparison of the intended use/indications for use and the non-clinical performance testing, it is concluded that the subject device is substantially equivalent to the predicate device.