July 25, 2025

Kelyniam Global Inc.
Elise Bozzuto
Quality Director
97 River Road, Suite A
Canton, Connecticut 06019

Re: K250334
Trade/Device Name: Fusion Craniofacial Implant; Fusion Skull Implant
Regulation Number: 21 CFR 882.5320
Regulation Name: Preformed Alterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: GWO
Dated: February 5, 2025
Received: February 5, 2025

Dear Elise Bozzuto:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 2025.07.25 15:32:38 -04'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine Devices
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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)*
K250334

Device Name
Fusion Craniofacial Implant (FCI);
Fusion Skull Implant (FSI)

Indications for Use *(Describe)*
Fusion Craniofacial Implant (FCI) and Fusion Skull Implant (FSI) are intended to fill a bony void or defect area in a patient's specific cranial and craniofacial skeleton (orbital rim, zygoma, and adjacent bone).

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.

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510(k) Summary

Date Prepared: 06/23/2025

Submitter Information:

Submitter:
Kelyniam Global Inc. (KGI)
97 River Road, Suite A
Canton, Connecticut 06019

Tel: (800) 280-8192
Fax: (501) 641-2000

Official Correspondent:
Elise Bozzuto
Quality Director
Tel: (800) 280-8192
Email: ebozzuto@kelyniam.com

Device Information:

Trade Name: Fusion Craniofacial Implant (FCI) and Fusion Skull Implant (FSI)
Common Name: Fusion Cranial/Skull Implant or Fusion Craniofacial Implant
Classification Information: Panel: Neurology / Product Code: GWO / Classification: Class II in accordance with 21 CFR 882.5320, Preformed Alterable Cranioplasty Plate.
Predicate Devices:

- Primary Predicates - K103582 Kelyniam Global Inc. (KGI) Customized Skull Implant (CSI); K121755 Kelyniam Global Inc. (KGI) Customized Craniofacial Implant (CCI); K182711 Kelyniam Global Inc. (KGI) Customized Craniofacial Implant (CCI), Customized Skull Implant (CSI).

Device Description: Fusion Craniofacial Implant (FCI) and Fusion Skull Implant (FSI) are individually sized and shaped implantable prosthetic plates intended to fill a bony void or defect area in a specific patient's cranial and craniofacial skeleton, ranging from 2 mm to 10 mm thick (typically 4mm thick based on the patient CT Scan imaging data) x 25mm to 250 mm wide x 25 mm to 250 mm long.

A Fusion Skull Implant (FSI) is intended to fill a bony void or defect area in a specific patient's skull, whereas a Fusion Craniofacial Implant (FCI) is intended to fill a bony void or defect area in a specific patient's facial region of the skull, excluding the Maxilla (upper jaw area surrounding the teeth only) and Mandible, both considered load bearing areas of the facial region of the skull.

The size, asymmetrical shape, thickness, contour, and edge profile are design elements of the

non-load bearing patient-specific base implant. These design elements are used to support the base implant in the bony void or defect area to provide a "Precise Fit."

The single-use alterable base implant (1) is fabricated from a billet block of implant grade Polyether ether ketone (PEEK) Thermoplastic Polymer formulated with biphasic calcium phosphate (BCP PEEK), using a patient's CT scan imaging data, (2) is provided clean (non-sterile) for steam sterilization prior to implantation at a hospital or surgical site, and (3) are attached to the native bone using commercially available cranioplasty hardware and fasteners.

Indications for Use: The Fusion Craniofacial Implant (FCI) and Fusion Skull Implant (FSI) are intended to fill a bony void or defect area in a patient's specific cranial and craniofacial skeleton (orbital rim, zygoma, and adjacent bone).

Intended Use: The Fusion Craniofacial Implant (FCI) and Fusion Skull Implant (FSI) are intended to treat infants to the elderly that suffer from a traumatic brain injury such as trauma, stroke, disease, tumor, infection, etc. whereby the patient's original bone will not be used.

Statement of Substantial Equivalence: The Kelyniam subject devices are intended to fill a bony void or defect area in a patient's specific Cranial and Craniofacial skeleton and are substantially equivalent in indications for use, technology, and material to:
K103582, K121755, and K182711 Kelyniam Global Inc. (KGI) Customized Craniofacial Implant (CCI), Customized Skull Implant (CSI) (Primary).

Comparison of Technological Characteristics with the Predicate Device(s): The Kelyniam subject devices are manufactured from implant grade Polyether ether ketone Thermoplastic Polymer material formulated with biphasic calcium phosphate, known hereafter as BCP PEEK, sold non-sterile, and intended to fill a bony void or defect area in a patient's specific Cranial and Craniofacial skeleton. This material is subject to the same design phase and manufacturing process as the Kelyniam cleared devices. This material is intended to facilitate enhanced bone in-growth following implantation, while not introducing any new technological issues. The Kelyniam subject device is identical to the cleared primary predicate devices in every way except for the proposed base material change and proposed labeling changes.
See Device Comparison Chart below for details.

	Subject Device	**Primary Predicates**		
Manufacturer	Kelyniam Global Inc. (KGI)	Kelyniam Global Inc. (KGI)		
510(k) #		K103582	K121755	K182711
Description	Fusion Craniofacial Implant (FCI), Fusion Skull Implant (FSI)	Customized Skull Implant (CSI)	Customized Craniofacial Implant (CCI)	Customized Craniofacial Implant (CCI), Customized Skull Implant (CSI)
Intended Use	Is intended to fill a bony void or defect area in a patient's specific cranial/craniofacial skeleton	Is intended to fill a bony void or defect area in a patient's specific cranial/craniofacial skeleton		
Material	Evonik Vestakeep iC4800R®	Evonik Vestakeep i4® or Invibio Inc PEEK-Optima LT-1®		

Technical Specification	Plate: Custom sized to each patient using CT scan data	Plate: Custom sized to each patient using CT scan data
Sterilization	Provided Non-sterile	Provided Non-sterile
Product Code	GWO (882.5320, Preformed Alterable Cranioplasty Plate)	GWO (882.5320, Preformed Alterable Cranioplasty Plate)
Classification	Class II	Class II

Performance Data:

Biocompatibility Testing: Evonik Industries has conducted the following biocompatibility testing on Vestakeep iC4800R® Polyether ether ketone (PEEK) material formulated with biphasic calcium phosphate, BCP PEEK. Results are included with this submission.

ISO 10993-3 Genotoxicity: Ames Test, ISO 10993-3 Genotoxicity: Mouse Lymphoma test, ISO 10993-5 Cytotoxicity, ISO 10993-6 Test for local effects after Implantation in bone (4 weeks), ISO 10993-6 Test for local effects after Implantation in bone (12 weeks), ISO 10993-6 Test for local effects after Implantation in bone (26 weeks), ISO 10993-10 Sensitization: Maximization test according to Magnusson and Kligman, ISO 10993-10 Irritation: Intracutaneous Reactivity, ISO 10993-11 Acute Systemic Toxicity, ISO 10993-11 Subchronic Systemic Toxicity, ISO 10993-12 GC/MS Fingerprint, Material-Mediated Pyrogens, USP Class VI Acute Systemic Toxicity, Intracutaneous Reactivity, Muscle Implantation.
Additional cytotoxicity testing and hemocompatibility testing were conducted separately on the subject devices.

Performance Testing: Evonik Vestakeep iC4800R® PEEK (BCP PEEK) Certification of Analysis/Certification of Compliance are reviewed and accepted when received against approved specifications, as part of receiving inspection activities.

Cleaning Validation: Testing was conducted for the submission of the Kelyniam cleared devices. The cleaning process of the subject devices are identical to that of the Kelyniam cleared devices. During the cleaning process, isopropyl alcohol is used as an antiseptic wipe. An accelerated ageing study performed by Evonik (raw material manufacturer) shows that no substances were reported from the gas-chromatography prepared from the extract using isopropanol, indicating that there are no deleterious effects from the use of isopropyl alcohol. The cytotoxicity tests performed on the materials confirm that no changes in the chemical composition of the materials could be detected. Neither the unaged material nor the sterilized and/or aged material showed signs of cytotoxicity.

Bacterial endotoxin testing was performed for the subject device. The testing determined endotoxins detected on finished devices were well below the maximum acceptable limits.

Steam Sterilization Validation: Testing was conducted in accordance with the following: ANSI/AAMI ST79. The finished product is shipped non-sterile, to be sterilized by the end-user. Sterilization recommendations are provided within the Instructions For Use (IFU).

Mechanical Testing Validation: There is no industry accepted standard governing mechanical testing for non-load bearing implantable prosthetic plates. A Mechanical Testing Validation Protocol was developed by Kelyniam to validate the subject devices.

Ship Testing Validation: Testing was conducted for the submission of the Kelyniam cleared devices. The packaging and shipping process of the subject devices is identical to that of the Kelyniam predicate devices.

Summary on Non-Clinical Testing: The testing performed on the subject devices demonstrates substantial equivalence to the predicate devices. The subject devices performed equivalent to the predicate devices during mechanical testing using a worst-case scenario.

Summary on Clinical Testing: Clinical Testing was determined not applicable for Kelyniam Global Inc. Fusion Craniofacial Implant (FCI) and Fusion Skull Implant (FSI).

Conclusion: The biocompatibility testing, steam sterilization testing, and mechanical testing of the subject devices were performed. The results of these tests, as well as additional product related validations (all samples passed the acceptance criteria) support the safety and effectiveness of the device and are substantially equivalent to the predicate devices.