May 21, 2019

Kelyniam Global Inc.
Eric Boyea
Quality Director
97 River Road, Suite A
Canton, Connecticut 06019

Re: K182711
Trade/Device Name: Customized Craniofacial Implant (CCI), Customized Skull Implant (CSI)
Regulation Number: 21 CFR 882.5320
Regulation Name: Preformed Alterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: GWO
Dated: April 15, 2019
Received: April 16, 2019

Dear Eric Boyea:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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, M.S.E.
Assistant Director
THT5A1: Neurosurgical Devices
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)*
K182711

Device Name
Customized Craniofacial Implant (CCI)
Customized Skull Implant (CSI)

Indications for Use *(Describe)*

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).

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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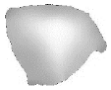
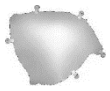
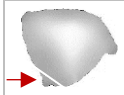
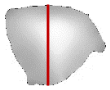
KELYNIAM

K182711 510(k) Summary

Date Prepared:	20MAY2019
Purpose:	
Purpose of the Submission:	The purpose for the Premarket Notification 510(k) is for authorization to add additional features to the currently cleared (devices) base implant or base implant with Prefusion Holes. The additional features do not alter the intended therapeutic use of the subject device, the technological characteristic nor do they affect the safety and effectiveness of the subject devices relative to the predicates. The additional features are intended to respond to requests by surgeons to facilitate the surgical application of the implant(s) and do not introduce any new technological issues. The base implant, as well as the proposed new features is fabricated from a billet block of natural implant grade Polyether ether ketone (PEEK) Thermoplastic Polymer. This is the same material currently used by the listed predicate device organizations.
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:	Eric Boyea, Director of Quality & Regulatory Affairs Toll Free: (800) 280-8192 x 701 Tel: (860) 352-5736 Email: eboyea@kelyniam.com
Device Information	
Trade Name:	• Customized Craniofacial Implant (CCI) and Customized Skull Implant (CSI)
Common Name:	• Customized Cranial Implant or Craniofacial/Skull 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 Predicate - K121153 Stryker PEEK Customized Cranial Implant Kit • Secondary Predicate - K053199 Synthes Patient Specific Cranial/Craniofacial Implant (PSCI) • Tertiary Predicate - K103582 Kelyniam Global Inc. (KGI) Customized Skull Implant (CSI) • Quaternary Predicate - K121755 Kelyniam Global Inc. (KGI) Customized Craniofacial Implant (CCI)
Device Description (with included features previously cleared):	Customized Craniofacial Implant (CCI) and Customized Skull Implant (CSI) is an 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 (orbital rim, zygoma, & adjacent bone), 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 Customized Skull Implant (CSI) is intended to fill a bony void or defect area in a specific patient's skull whereas a Customized Craniofacial Implants (CCI) 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, which are 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 that are used to support the base implant in the bony void or defect area while providing for a "Precise Fit". The single patient use base implant is (1) fabricated from a billet block of natural implant grade Polyether ether ketone (PEEK) Thermoplastic Polymer using the patient's CT Scan imaging data, (2) provided clean but non-sterile for steam sterilization prior to implantation at a hospital or surgical site with neurosurgery capabilities, and (3) attached to the native bone using commercially available cranioplasty hardware and fasteners. The additional features listed below are additional design elements that may be added to the Base Implant and Base Implant with Perfusion Holes, as requested by the Physician.
	 The Base Implant, as defined above (as previously cleared on K103582 and K121755).
	 Perfusion Holes are a design element that allow the passage of fluid to an organ or tissue (as previously cleared on K103582 and K121755).

K182711 510(k) Summary

Device Information (Continued)

Additional Features (Subject of this submission):		Integrated Fixation System (IFS) or IFS Tabs are a design element used to fixate the Base Implant to the patient's cranial and craniofacial skeleton using commercially available cranioplasty screws; replacing the need to fixate the Base Implant using commercially available cranioplasty hardware while maintaining a "Precise Fit".
		A Temporal Cutback is a design element, if requested by a Physician, that dictates the shape of the Base Implant in the temporal fossa region of the patient's cranial skeleton to aid in reducing intraoperative tissue trauma or temporalis muscle damage during the cranioplasty surgery.
		A Multi-Part Implant is a design element that is used for patients with a bony void or defect area that cannot be filled using a single Base Implant. A Multi-Part Implant is used when (1) the overall implant contour or curvature height exceeds the overall thickness of the billet block of natural implant grade Polyether ether ketone (PEEK) Thermoplastic Polymer, (2) the geometry of the Base Implant causes undercuts, or (3) the Base Implant is non-passive requiring the implants to be installed separately while maintaining a "Precise Fit".
Indications for Use:	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).	
Statement of Substantial Equivalence:	The KGI 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 K121153 Stryker PEEK Customized Cranial Implant Kit (Primary), K053199 Synthes Patient Specific Cranial/Craniofacial Implant (PSCI) (Secondary), K103582 KGI Customized Skull Implant (CSI) (Tertiary), and K121755 KGI Customized Craniofacial Implant (CCI) (Quaternary).	
Comparison of Technological Characteristics with the Predicate Device(s):	The KGI subject devices are manufactured from implant grade Polyether ether ketone Thermoplastic Polymer material, known hereafter as PEEK, sold non-sterile, and is intended to fill a bony void or defect area in a patient's specific Cranial and craniofacial skeleton. The additional features, as listed above, are incorporated in the Base Implant during the design phase and CNC Machined from a billet block of PEEK. The additional features are intended to respond to requests by surgeons to facilitate the surgical application of the implant(s) and do not introduce any new technological issues. See Device Comparison Chart below for details.	

Subject Devices vs Predicate Devices Comparison Chart with included Additional Features

	Subject Device	Subject Device	Primary Predicate	Secondary Predicate	Tertiary Predicate	Quaternary Predicate
Manufacturer	Kelyniam Global Inc. (KGI)		Stryker	Synthes	Kelyniam Global Inc. (KGI)	
510(k) #	K182711		K121153	K053199	K103582	K121755
Description	Customized Craniofacial Implant (CCI)	Customized Skull Implant (CCI)	PEEK Customized Craniofacial Implant Kit	Patient Specific Cranial/ Craniofacial Implant (PSCI)	Customized Skull Implant (CSI)	Customized Craniofacial Implant (CCI)
Indications for Use	Is intended to fill a bony void or defect area in a patient's specific cranial and craniofacial skeleton (orbital rim, zygoma, & adjacent bone)		Is intended to be used to replace bony voids in the cranial/craniofacial skeleton	Is intended to replace bony voids in the Cranial/ craniofacial skeleton	Is intended to fill a bony void or defect area in a patient's specific cranial and craniofacial skeleton	
Material	Invibio Inc PEEK-Optima LT-1® and Evonik Vestakeep i4®		Invibio Inc PEEK-Optima LT-1®	CP Titanium and PEEK	Invibio Inc PEEK-Optima LT-1®	
Technical Specification	Plate - Custom sized to each patient using CT scan data		Customized patient-specific implant based on CT scan data	Implants are preformed/pre-shaped to fit the anatomy of the patient	Custom sized to each patient using CT scan data	
Sterilization	Provided Non-sterile		Provided Non-sterile	Provided Non-sterile	Provided Non-sterile	
Product Code	GWO (882.5320, Preformed Alterable Cranioplasty Plate)		GWO	GXN	GXN (882.5330, Preformed Non-alterable Cranioplasty Plate)	
Classification	Class II		Class II	Class II	Class II	
Perfusion Holes	X	X	X	-	X	X
IFS	X	X	-	-	-	-
Temporal Cutback	X	X	-	-	-	-
Multi-Part Implant	X	X	-	X	-	-

K182711 510(k) Summary

Performance Data

Performance Data Biocompatibility Testing: Performance data has been provided in support of the substantial equivalence determination	• Biocompatibility was leveraged from previously cleared devices. A risk assessment was conducted to evaluate the impact of design changes on the biocompatibility of subject device. The results demonstrate that the subject device meets biological safety requirements per ISO 10993-1 for permanently implanted devices that have tissue/bone and cerebrospinal fluid contact.

Performance Testing Bench: Performance data has been provided in support of the verification & validation testing conducted for a determination of substantially equivalence. The subject devices are safe, effective, and substantially equivalent to the predicate devices.	• Invibio PEEK Optima LT-1® and Evonik Vestakeep i4® Material Specifications and Certification of Analysis/Certification of Compliance
	  ○ ASTM F2026-16 Standard Specification for Polyether ether ketone (PEEK) Polymers for Surgical Implant Applications.
	  ○ PEEK Certification of Analysis/Certification of Compliance are reviewed and accepted against approved specifications at each receipt as part of receiving inspection activities.
	• Cleaning Validation testing was conducted in accordance with the following:
	  ○ ANSI/AAMI ST72:2011 Bacterial endotoxins, Test methods, routine monitoring, and alternatives to batch testing.
	  ○ USP <161>, USP <85>, EP 2.6.14, and JP 4.01. USP <85> Bacterial Endotoxin Test (BET).
	• Steam Sterilization Validation testing was conducted in accordance with the following:
	  ○ ANSI/AAMI/ISO 17665-1:2006, Sterilization of health care products - Moist heat - Part 1 - Requirements for the development, validation, routine control of a sterilization process for medical devices, Annex D.
	  ○ ANSI/AAMI/ISO 14937:2009, Sterilization of health care products, general requirements for characterization of a sterilizing agent & development, validation, and routine control of a sterilization process for medical devices, Annex D.
	• 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 KGI to validate the subject devices.
	• Ship Testing Validation testing was conducted in accordance with the following:
	  ○ FedEx Packaging Testing Under 150Lb (Same as ITSA-2A-2011 Packaged-Products 150 lb (68 kg) or Less)

Summary on Non-Clinical Testing:	The safety and compatibility of passive implants in the Magnetic Resonance (MR) environment concern magnetically induced displacement force and torque, radio frequency (RF) heating, and image artifacts. The static magnetic field of the MR system induces displacement forces and torques on magnetic materials: The Kelyniam Global Inc. (KGI) implants are electrically nonconductive or a nonmagnetic item and poses no known hazards in all MR environments. The KGI Customized Craniofacial (CCI) and Customized Skull (CSI) Implants are MR Safe.
Summary on Clinical Testing:	Clinical Testing was determined not applicable for Kelyniam Global Inc. Customized Craniofacial Implant (CCI) and Customized Skull Implant (CSI).
Conclusion:	The biocompatibility testing, steam sterilization testing, cleaning testing, mechanical testing, and ship testing of the subject devices with and without the proposed features was performed and the results of these tests as well as additional product related validations (all samples passed the acceptance criteria) support the device is safe and effective and substantially equivalent to the predicate devices.