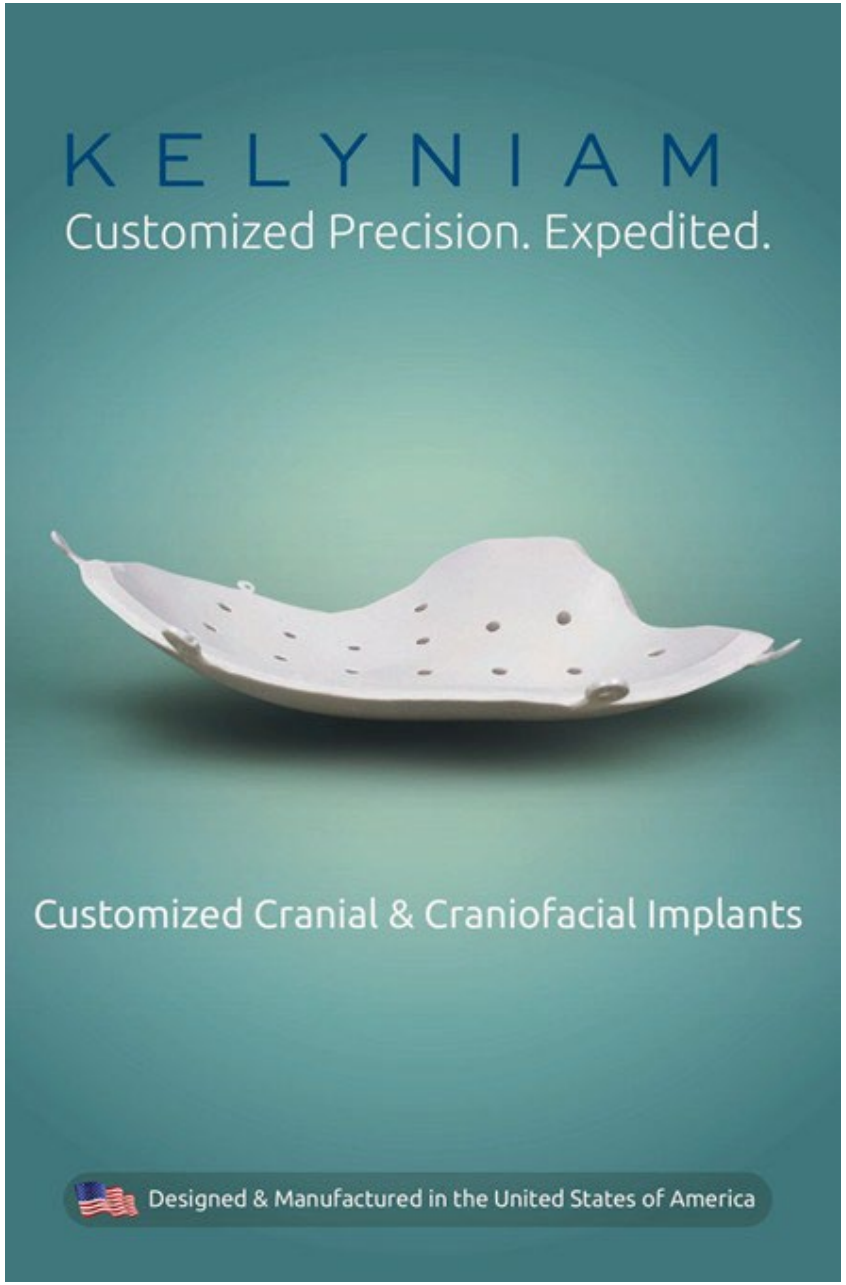
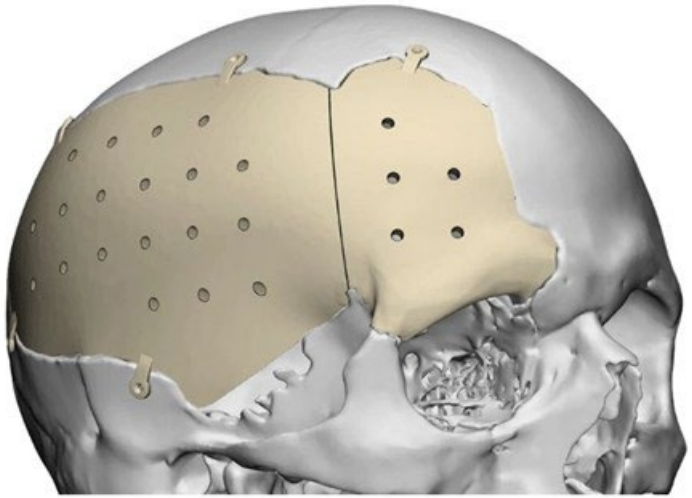


Value Analysis Committee
New Product Approval Package

Kelyniam is requesting approval of its cranial surgical portfolio of products for use in indicated cranioplasty and craniofacial reconstruction cases under hospital-approved ordering and case-review protocols.

Kelyniam Global, Inc.
97 River Road, Suite A
Canton, CT 06019
M-F: 8:30-5:00 EST
P. 800.280.8192
F. 501.641.2000
info@kelyniam.com



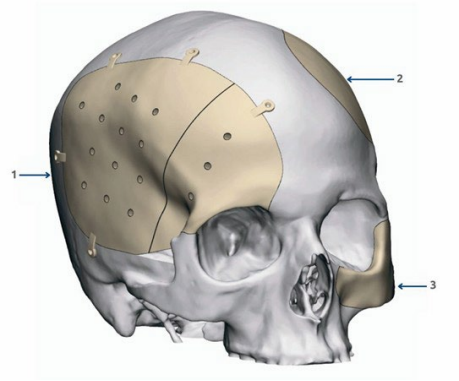
Precision Craniofacial Solutions with Unmatched Speed-to-Surgery

Kelyniam Global provides U.S. hospitals with a comprehensive portfolio of patient-specific implants (PSIs) and regenerative biomaterials designed to optimize clinical outcomes while reducing total cost of care.

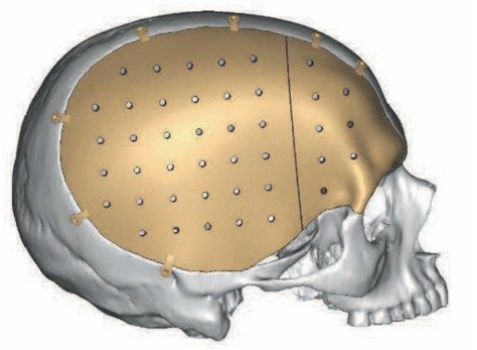
Our flagship **Custom PEEK Cranial and Craniofacial Implants** feature a patented Integrated Fixation System (IFS), which streamlines the surgical workflow by reducing or eliminating the need for expensive additional cranial plating. To further optimize recovery, our next-generation **Fusion™ Implants** promote accelerated osseointegration through osteoconductive properties.

We also provide the following products: **Finceramica CustomizedBone™** biomimetic hydroxyapatite implants, which offer unmatched biocompatibility for complex cranial reconstructions; **Osteopore®** bioresorbable scaffolds, which promote natural bone regrowth for Burr holes and craniotomies; and the **NEOS Cranial Loop™**, a cranial fixation device for securing bone flaps.

Kelyniam Product Portfolio

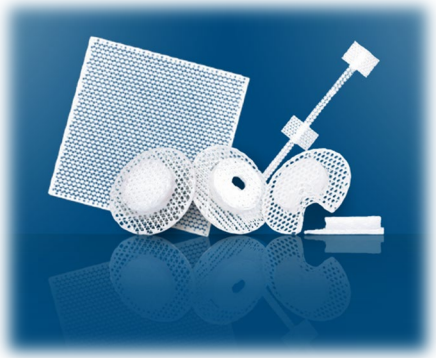


Customized Craniofacial Implant (CCI)
Customized Skull Implant (CSI)



Fusion Craniofacial Implant (FCI)
Fusion Skull Implant (FSI)

CustomizedBone™ Service
Patient Specific Hydroxyapatite Implant



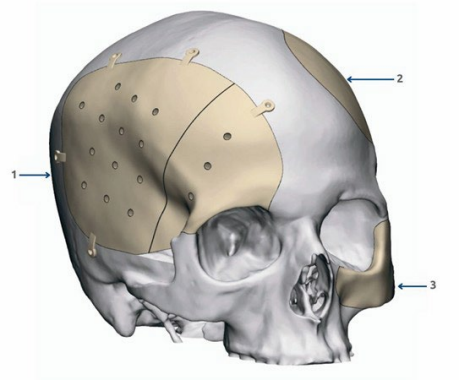
Osteopore®
Regenerative Bone Scaffold

NEOS Surgery Cranial Loop™
Smart Cranial Fixation System

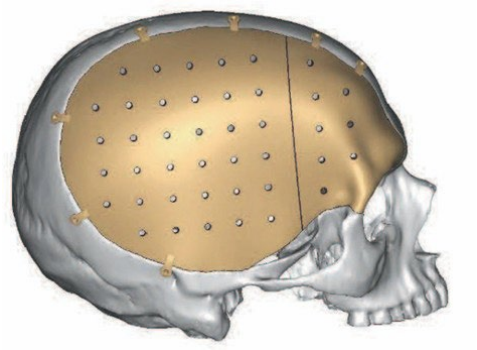
TABLE OF CONTENTS

*Contains: Product Brochure, IFU, 510(k) Clearance, ISO Certifications, CT Scan Protocols, Clinical Literature, Price List, W-9, Clinical Champion Letter

Kelyniam Product Portfolio

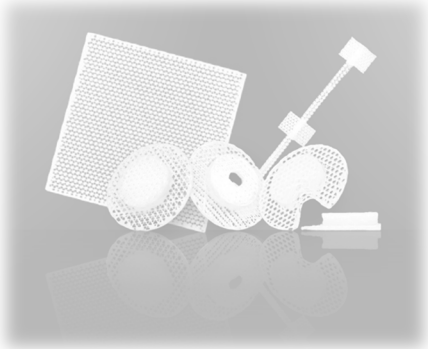


Customized Craniofacial Implant (CCI)
Customized Skull Implant (CSI)



Fusion Craniofacial Implant (FCI)
Fusion Skull Implant (FSI)

CustomizedBone™ Service
Patient Specific Hydroxyapatite Implant



Osteopore®
Regenerative Bone Scaffold

NEOS Surgery Cranial Loop™
Smart Cranial Fixation System

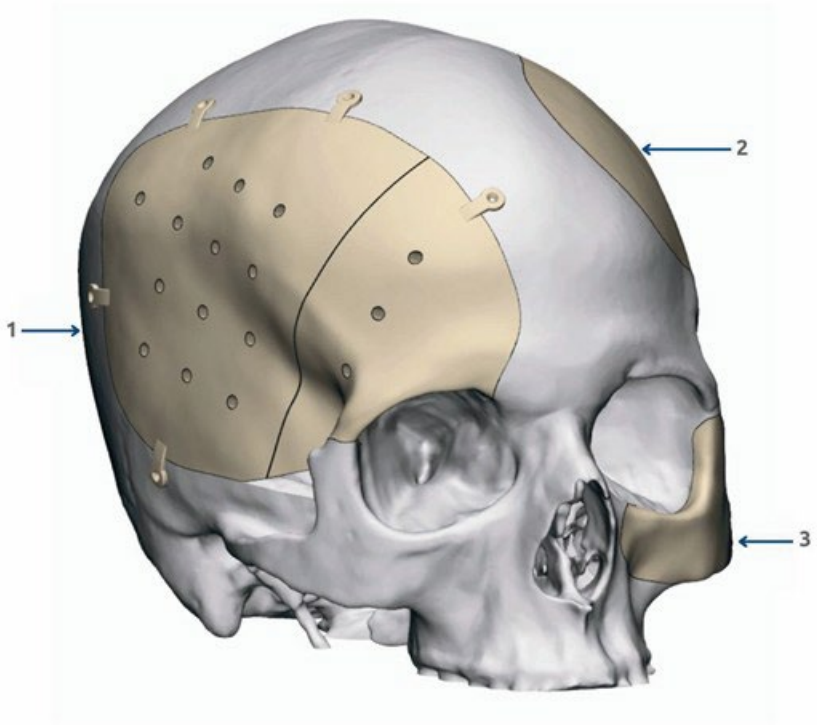
Product name:	**Kelyniam Custom Cranial and Craniofacial PEEK Implant**
Manufacturer:	**Kelyniam, Inc.**
Product type:	**Patient-specific implantable medical device**
Service line:	**Neurosurgery**
Request type:	**New product approval**
Physician champion:	
Sales rep contact:	
Date of submission:	
Requested committee action:	

Executive Summary

- A formal letter of request by Dr. _____ has been submitted for approval of Kelyniam patient-specific PEEK plates (Appendix A)
- Kelyniam's customized cranial PEEK implant is a **patient-specific solution** designed from CT DICOM data to achieve a precise fit for cranial defects.
- Kelyniam's **Integrated Fixation System** may reduce or eliminate the need for separate cranial plating, with the potential to reduce operating time and overall case cost.
- For urgent cases, Kelyniam can deliver custom implants **within 24–48 hours of surgeon approval**, which may support faster treatment planning for in-house patients.
- To meet any domestic sourcing requirements, all Kelyniam customized PEEK plates are **manufactured in the USA**

Product Overview

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

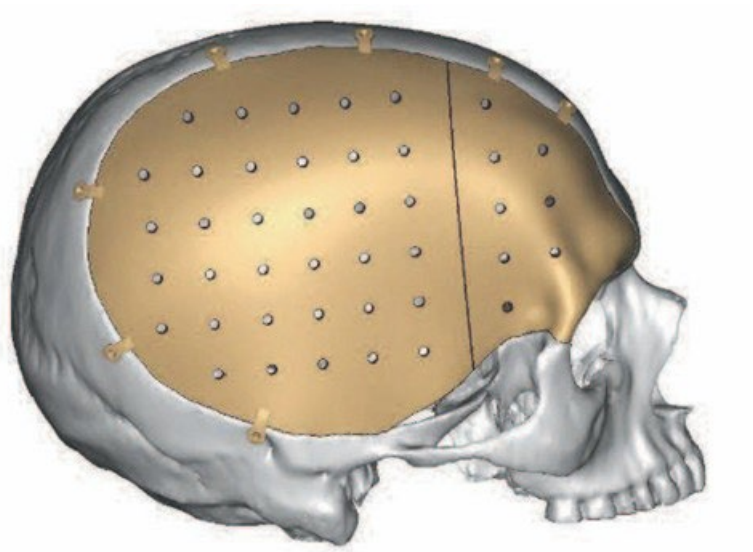


1. Multi-Part Customized Skull Implant (CSI) with Perfusion Holes, Integrated Fixation System (IFS), and Temporal Cutback.
2. Customized Skull Implant (CSI) without Perfusion Holes.
3. Customized Craniofacial Implant (CCI) without Perfusion Holes.

- *Intended to fill a bony void or defect area in a patient's specific cranial and craniofacial skeleton.*
- **PEEK Material** has been shown to have benefits over standard metal plates like titanium.
- **Integrated Fixation System (IFS) Tabs** secure implant with cranioplasty fixation screws which may decrease OR time and cost savings.
- **Perfusion Holes** can be equally spaced across implant to allow for passage of fluid.
- **Temporal Cutback** aids in reducing intraoperative tissue trauma or temporalis muscle damage.
- **Multi-Part Implant** when defect is too large or will simplify the surgery.
- **3D Surgical Models** available upon request for surgical planning and illustration.
- Optional **24-48 hours delivery** for emergent cases
- All customized PEEK plates are **manufactured in the USA.**

Product Overview

Fusion Craniofacial Implant (FCI)
Fusion Skull Implant (FSI)



- *Intended to fill a bony void or defect area in a patient's specific cranial and craniofacial skeleton.*
- **Fusion BCP PEEK Material** infused with Biphasic Calcium Phosphate facilitates enhanced bone in-growth which may decrease incidence of post-surgical infections.
- **Integrated Fixation System (IFS) Tabs** secure implant with cranioplasty fixation screws which may decrease OR time and cost savings.
- **Perfusion Holes** can be equally spaced across implant to allow for passage of fluid.
- **Temporal Cutback** aids in reducing intraoperative tissue trauma or temporalis muscle damage.
- **Multi-Part Implant** when defect is too large or will simplify the surgery.
- **3D Surgical Models** available upon request for surgical planning and illustration.
- Optional **24-48 hours delivery** for emergent cases
- All customized PEEK plates are **manufactured in the USA.**

Product Codes for Ordering

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

Customized Craniofacial Implant (CCI)	
Product Code	*Product Description*
PEEK-IM2001	Customized Craniofacial Implant, Small
PEEK-IM2002	Customized Craniofacial Implant, Medium
PEEK-IM2003	Customized Craniofacial Implant, Large
PEEK-IM2004	Customized Craniofacial Implant, X-Large

Customized Skull Implant (CSI)	
Product Code	*Product Description*
PEEK-IM1001	Customized Skull Implant, Small
PEEK-IM1002	Customized Skull Implant, Medium
PEEK-IM1003	Customized Skull Implant, Large
PEEK-IM1004	Customized Skull Implant, X-Large

Customized Craniofacial Implant (CCI) with IFS Tabs	
Product Code	*Product Description*
PEEK-IM2001-TABS	Customized Craniofacial Implant, Small w IFS
PEEK-IM2002-TABS	Customized Craniofacial Implant, Medium w IFS
PEEK-IM2003-TABS	Customized Craniofacial Implant, Large w IFS
PEEK-IM2004-TABS	Customized Craniofacial Implant, X-Large w IFS

Customized Skull Implant (CSI) with IFS Tabs	
Product Code	*Product Description*
PEEK-IM1001-TABS	Customized Skull Implant, Small w IFS
PEEK-IM1002-TABS	Customized Skull Implant, Medium w IFS
PEEK-IM1003-TABS	Customized Skull Implant, Large w IFS
PEEK-IM1004-TABS	Customized Skull Implant, X-Large w IFS

Product Codes for Ordering

Fusion Craniofacial Implant (FCI)
Fusion Skull Implant (FSI)

Fusion Craniofacial Implant (FCI)	
Product Code	*Product Description*
FUSION-IM4001	Fusion Craniofacial Implant, Small
FUSION-IM4002	Fusion Craniofacial Implant, Medium
FUSION-IM4003	Fusion Craniofacial Implant, Large
FUSION-IM4004	Fusion Craniofacial Implant, X-Large

Fusion Skull Implant (FSI)	
Product Code	*Product Description*
FUSION-IM3001	Fusion Skull Implant, Small
FUSION-IM3002	Fusion Skull Implant, Medium
FUSION-IM3003	Fusion Skull Implant, Large
FUSION-IM3004	Fusion Skull Implant, X-Large

Fusion Craniofacial Implant (FCI) with IFS Tabs	
Product Code	*Product Description*
PEEK-IM4001-TABS	Fusion Craniofacial Implant, Small w IFS
PEEK-IM4002-TABS	Fusion Craniofacial Implant, Medium w IFS
PEEK-IM4003-TABS	Fusion Craniofacial Implant, Large w IFS
PEEK-IM4004-TABS	Fusion Craniofacial Implant, X-Large w IFS

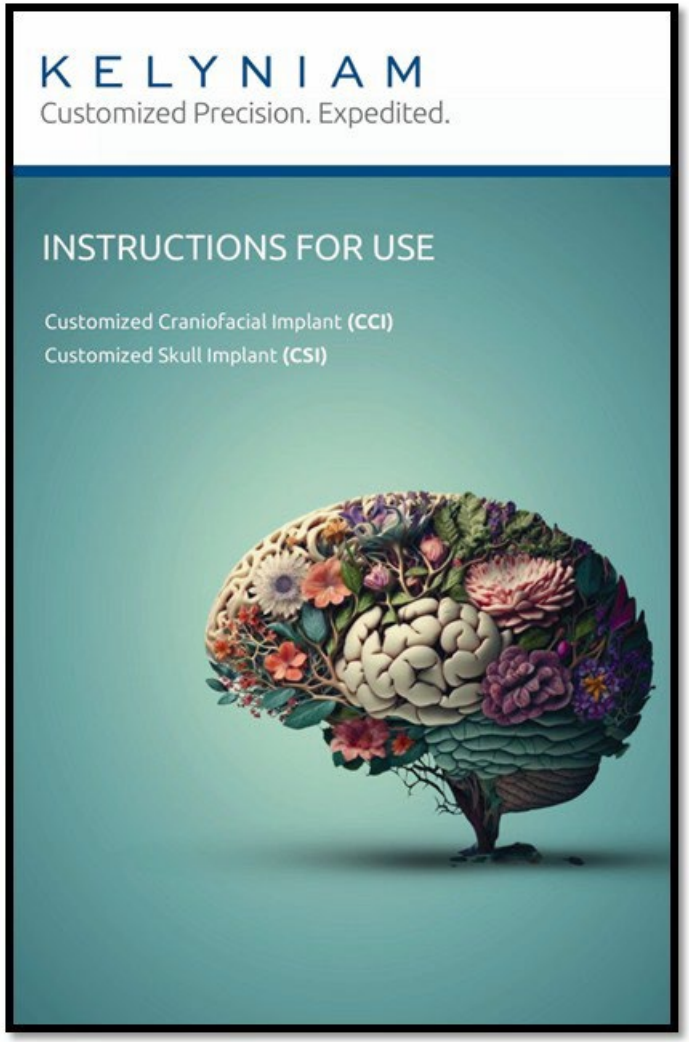
Fusion Skull Implant (FSI) with IFS Tabs	
Product Code	*Product Description*
FUSION-IM3001-TABS	Fusion Skull Implant, Small w IFS
FUSION-IM3002-TABS	Fusion Skull Implant, Medium w IFS
FUSION-IM3003-TABS	Fusion Skull Implant, Large w IFS
FUSION-IM3004-TABS	Fusion Skull Implant, X-Large w IFS

Product Codes for Ordering
Additional Features & Services

Surgical Model Kit	
Product Code	*Product Description*
SM-KIT1001	SM-KIT, Partial Host Bone with Acetal Defect Model
SM-KIT1002	SM-KIT, Full Host Bone with Acetal Defect Model
SPEC-CG	Cutting Guide, Custom Design

Additional Services	
Product Code	*Product Description*
KE24	24-48 Hours Expedited Service
SPEC-CCF	Complex Case Design Service

Intended Use



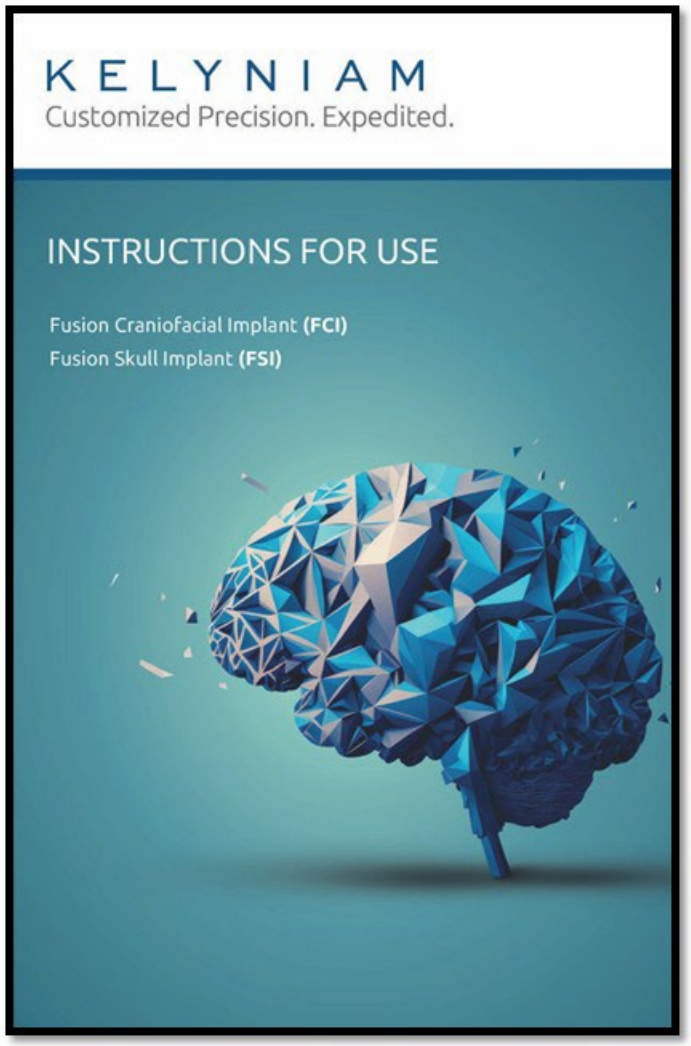
INDICATIONS FOR USE

The Customized Craniofacial Implant (CCI) and Customized Skull Implant (CSI) are intended to fill a bony void or defect area in a patient's cranial and craniofacial skeleton (orbital rim, zygoma, & adjacent bone).

DESCRIPTION OF DEVICE

Customized Craniofacial Implants (CCI) and Customized Skull Implants (CSI), known hereafter as Implant, are individually sized and shaped custom implantable prosthetic plates intended to fill a bony void or defect area in a specific patient's cranial and craniofacial skeleton (orbital rim, zygoma, and adjacent bone). 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 (known hereafter as 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. Additional features, as described below, are design elements that may be added to the Base Implant, as requested by the Physician.

Intended Use



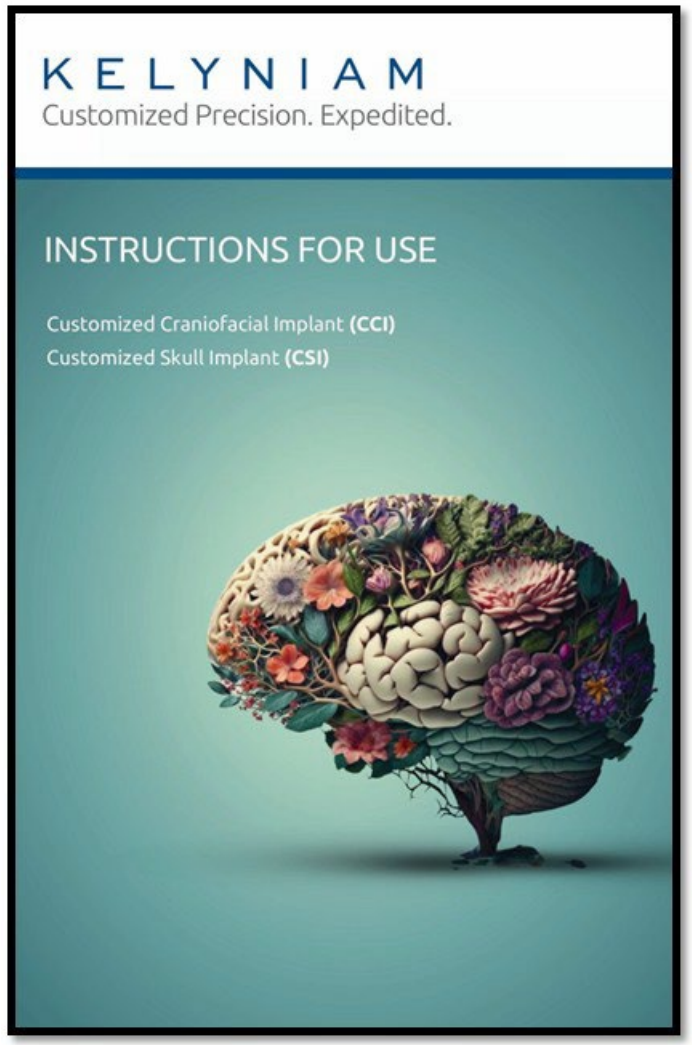
INDICATIONS FOR USE

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

DESCRIPTION OF DEVICE

Fusion Craniofacial Implants (FCI) and Fusion Skull Implants (FSI), known hereafter as Implant, are individually sized and shaped custom implantable prosthetic plates intended to fill a bony void or defect area in a specific patient's cranial and craniofacial skeleton (orbital rim, zygoma, and adjacent bone). 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 (known hereafter as 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. Additional features, as described below, are design elements that may be added to the Base Implant, as requested by the Physician.

Sterilization Instructions



STERILIZATION

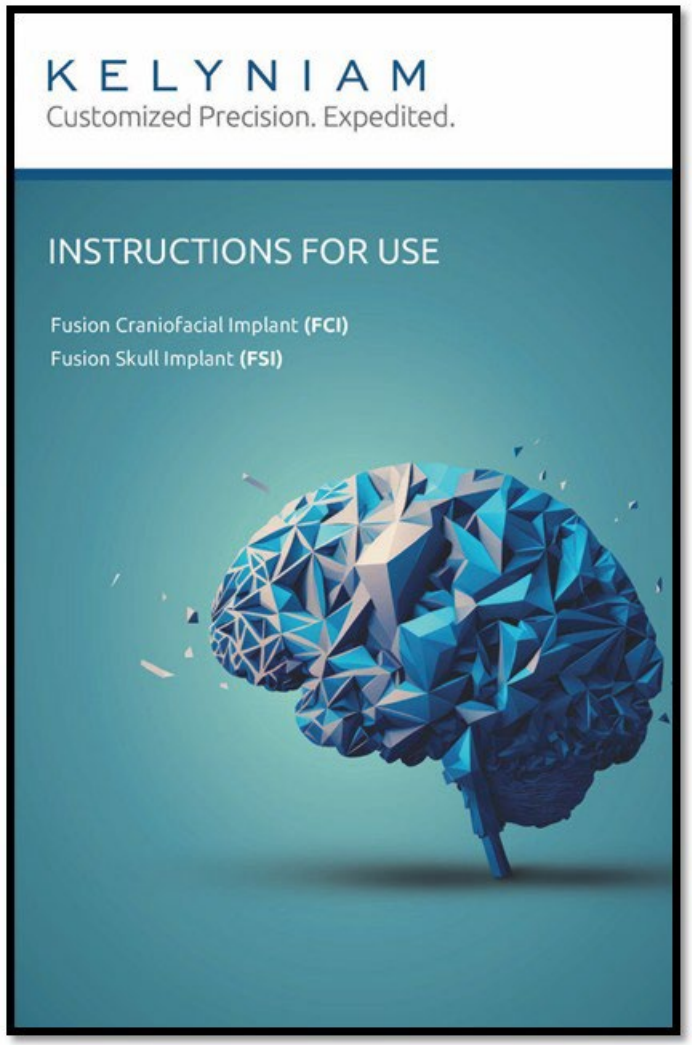
The Implants are supplied clean but NON-STERILE and should be repackaged before steam sterilization. Prior to steam sterilization, wrap the Implant with an FDA cleared biological indicator in 2 layers of 1-ply FDA cleared polypropylene sterilization wrap using sequential envelope folding techniques. Sterilize the Implant using the hospital or surgical site internal procedure for the method of steam sterilization to be performed. The recommended parameters listed below are based on 3rd party Laboratory testing conducted by Kelyniam Global Inc. (KGI) to establish sterility. These are in accordance with ANSI/AAMI ST79 - Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities.

CAUTION - Kelyniam Global, Inc. (KGI) is not liable for any data supplied by any 3rd party testing facility.

RECOMMENDATIONS FOR STEAM STERILIZATION

Sterilization Method	Wrapping Method	Sterilizer Type	Preconditioning Pulses	Minimum Temperature Exposure	Full Cycle Time	Dry Time
Steam	Wrap the device in two layers of FDA cleared polypropylene sterilization wrap (i.e. Halyard Health H600 Sterilization Wrap) using sequential envelope folding techniques.	Pre-vacuum	4	132°C (270°F)	4 minutes	30 minutes

Sterilization Instructions



STERILIZATION

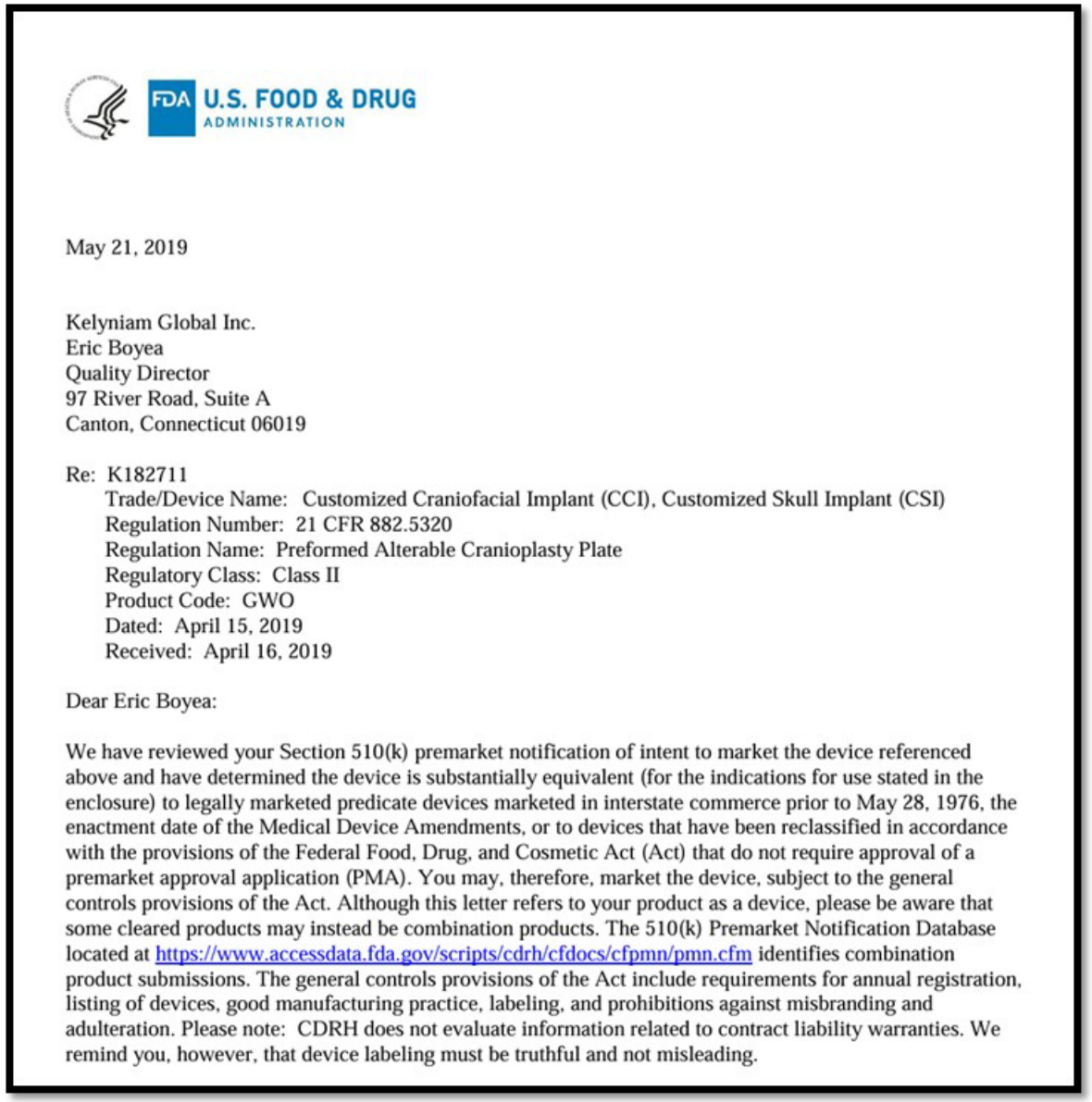
The Implants are supplied clean but NON-STERILE and should be repackaged before steam sterilization. Prior to steam sterilization, wrap the Implant with an FDA cleared biological indicator in 2 layers of 1-ply FDA cleared polypropylene sterilization wrap using simultaneous envelope folding techniques. Sterilize the Implant using the hospital or surgical site internal procedure for the method of steam sterilization to be performed. The recommended parameters listed below are based on 3rd party Laboratory testing conducted by Kelyniam Global Inc. (KGI) to establish sterility. These are in accordance with ANSI/AAMI ST79 - Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities.

CAUTION - Kelyniam Global, Inc. (KGI) is not liable for any data supplied by any 3rd party testing facility.

RECOMMENDATIONS FOR STEAM STERILIZATION

Sterilization Method	Wrapping Method	Sterilizer Type	Preconditioning Pulses	Minimum Temperature Exposure	Full Cycle Time	Dry Time
Steam	Wrap the device in two layers of FDA cleared polypropylene sterilization wrap (i.e. Halyard Health H600 Sterilization Wrap) using simultaneous envelope folding techniques.	Pre-vacuum	4	132°C (270°F)	4 minutes	30 minutes

Regulatory / Quality



U.S. FOOD & DRUG ADMINISTRATION

May 21, 2019

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

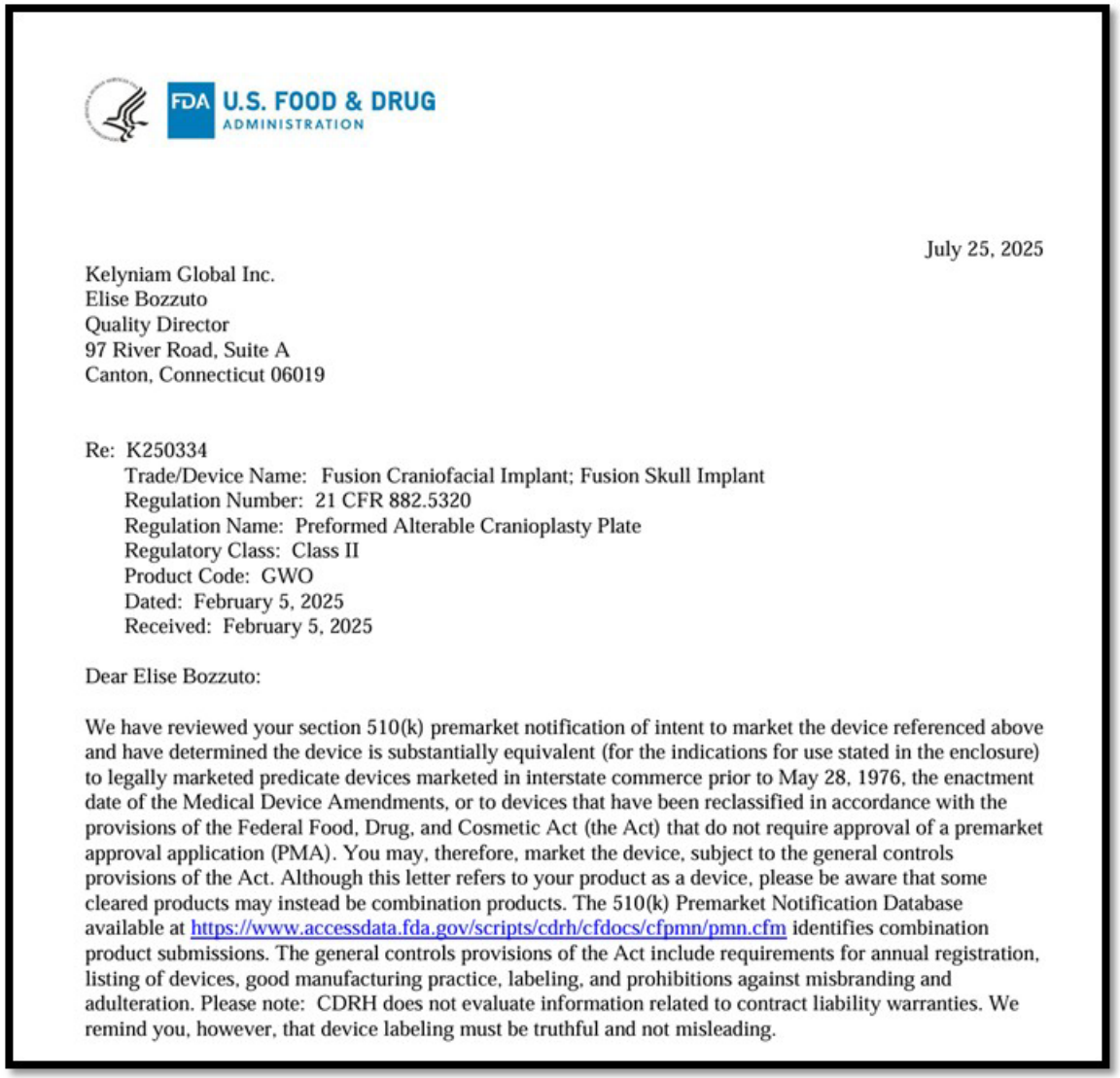
Re: K182711
Trade/Device Name: Customized Craniofacial Implant (CCI), Customized Skull Implant (CSI)
Regulation Number: 21 CFR 882.5320
Regulation Name: Preformed Alterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: GWO
Dated: April 15, 2019
Received: April 16, 2019

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.

510(k) Clearance for:
Customized Craniofacial Implant (CCI)
Customized Skull Implant (CSI)

Regulatory / Quality



U.S. FOOD & DRUG ADMINISTRATION

July 25, 2025

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

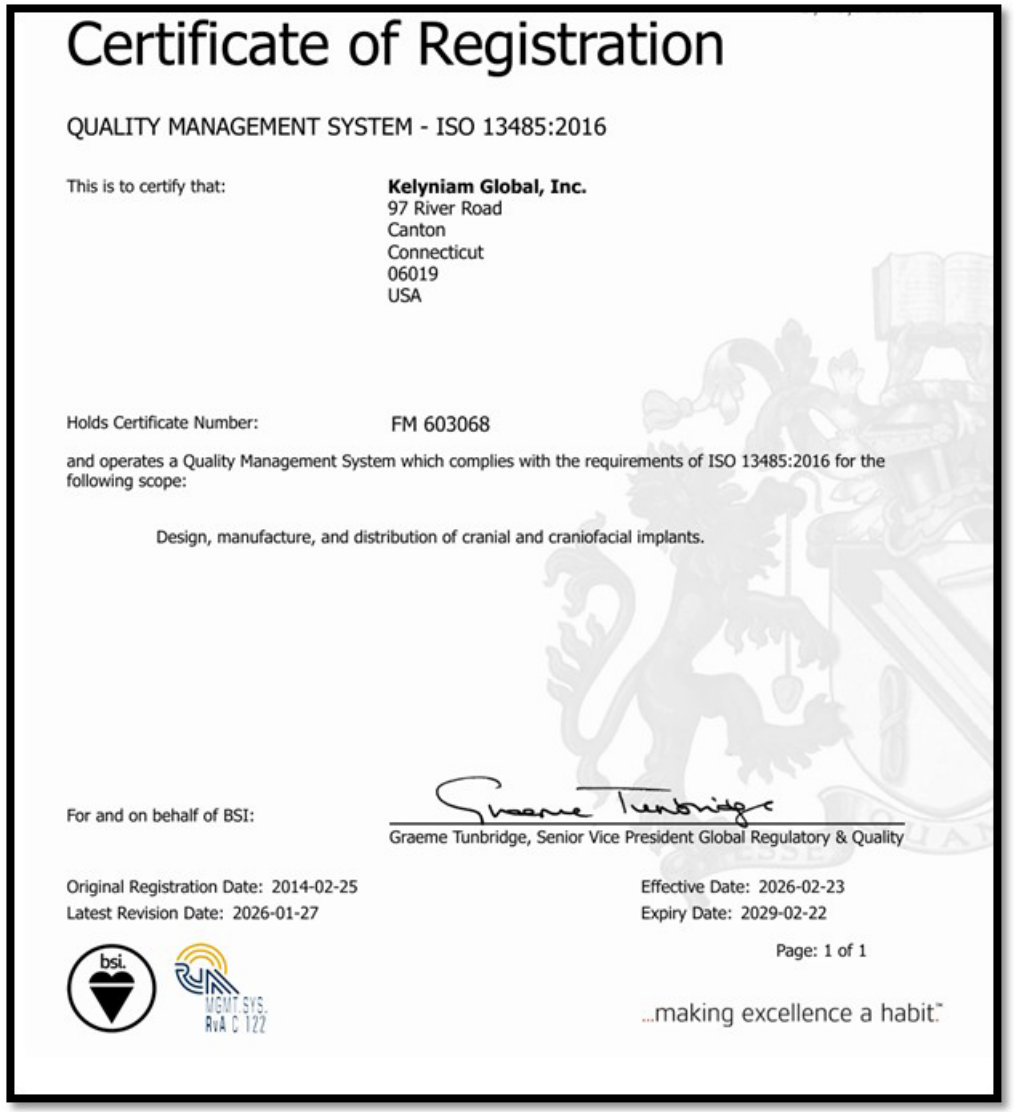
Re: K250334
Trade/Device Name: Fusion Craniofacial Implant; Fusion Skull Implant
Regulation Number: 21 CFR 882.5320
Regulation Name: Preformed Alterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: GWO
Dated: February 5, 2025
Received: February 5, 2025

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.

510(k) Clearance for:
Fusion Craniofacial Implant (FCI)
Fusion Skull Implant (FSI)

Regulatory / Quality



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Kelyniam Global, Inc.
97 River Road
Canton
Connecticut
06019
USA

Holds Certificate Number: FM 603068

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design, manufacture, and distribution of cranial and craniofacial implants.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2014-02-25
Latest Revision Date: 2026-01-27

Effective Date: 2026-02-23
Expiry Date: 2029-02-22

Page: 1 of 1

...making excellence a habit.™

ISO 13485:2016
Certification for Kelyniam Global, Inc.

KELYNIAM COMPLAINT HANDLING

PROCESS OVERVIEW

HOW TO SUBMIT

Call 800-280-8192 or email info@kelyniam.com.

Complaints may be verbal or written.

INTAKE & LOGGING

Any employee forwards to Quality Assurance (QA) within 48 hours.

QA assigns Complaint number & logs it.

ASSESSMENT & INVESTIGATION

QA/SME evaluates severity & risk. Determines if MDR reporting, CAPA, deviations, or noncon-formance are required. Conducts investigation.

RESOLUTION TIMELINE

Target closure within 30 calendar days of receipt (expedited if risk dictates).

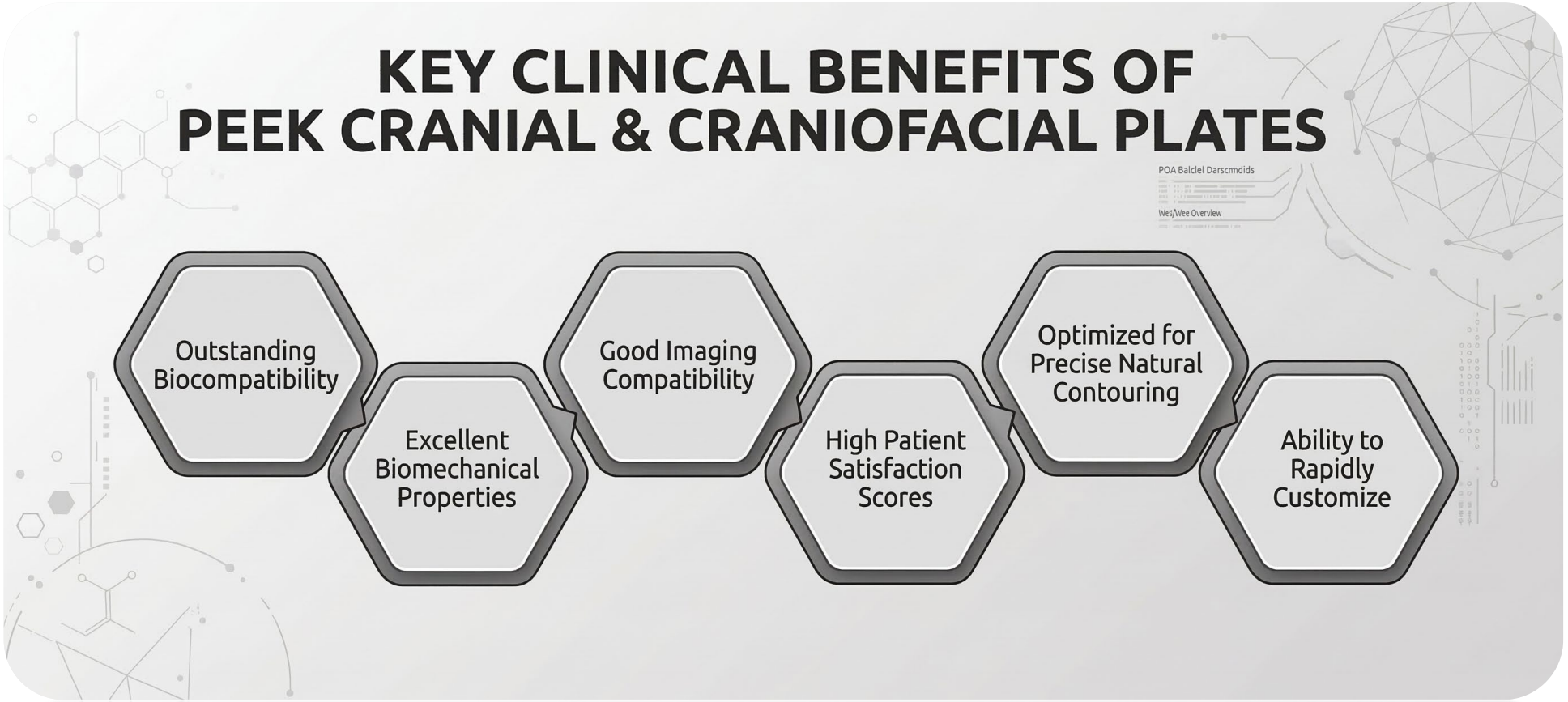
CLOSURE & COMMUNICATION

QA documents remediation, closes the record, and communicates as appropriate.

TRENDING & OVERSIGHT

Complaints trended annually. Reviewed in Management Review/Quality meetings.

Clinical Evidence Summary



PubMed-indexed clinical literature supports patient-specific PEEK as a safe and effective alternative to titanium for cranial reconstruction, with comparable overall outcomes and potential advantages in revision risk, implant exposure, contour restoration, and patient-reported satisfaction in selected studies

Citation	Finding
Henry J. et al. Complications of cranioplasty in relation to material. Neurosurgery. 2021 Aug 16;89(3):383-394.	PEEK appears to have the lowest risk of cranioplasty revision, but further research is required to determine the optimal material.
Liu L. et al. Comparison of complications in cranioplasty with various materials: a systematic review and meta-analysis. Br J Neurosurg. 2020 Aug;34(4):388-396.	PEEK has lower overall complication rates (OR, 0.51; 95% CI, 0.30-0.87, p = 0.01) and lower implant exposure rates (OR, 0.17; 95% CI, 0.06-0.53, p = 0.002) than Ti, but there was no significant difference in infection rates and postoperative hematoma.
Assad M. et al. Surgical and patient-reported outcomes in patients with PEEK vs. titanium cranioplasty reconstruction. J Craniofac Surg. 2021 Jan-Feb;32(1):193-197.	All PEEK cranioplasty patients who responded to the study survey (n = 13) reported good to excellent satisfaction.
Zegers T. et al. The therapeutic effect of patient-specific implants in cranioplasty. J Craniomaxillofac Surg. 2017 Jan;45(1):82-86.	Reconstruction of skull bone defects with PEEK (n=21/29) and titanium patient specific implants gave a statistically significant improvement in quality of life. Furthermore, it decreased pain and headaches and gave aesthetically good results.
Mursch K. et al. Polyether ether ketone cranioplasties are permeable to diagnostic ultrasound. World Neurosurg. (2018) 117:142-143.	When appropriate, for patients who are at risk for future vascular problems or hydrocephalus and require a cranial implant, PEEK may harbor advantages over other materials.

Kelyniam FUSION Plates May Offer Important Osseointegration Benefit for Patient Recovery

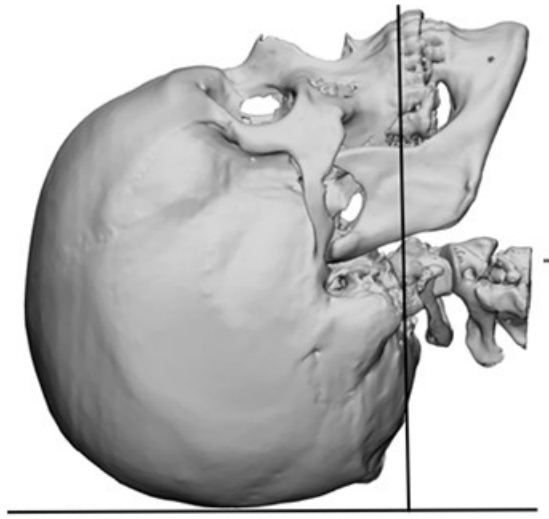
Published preclinical and limited clinical literature suggests that calcium-phosphate modification of PEEK may enhance osseointegration and early bone apposition. However, direct clinical evidence in cranial implants demonstrating that PEEK with biphasic calcium phosphate reduces postoperative infection is limited.

Citation	Finding
Zhu C, et al. Titanium-interlayer mediated hydroxyapatite coating on polyetheretherketone: a prospective study in patients with single-level cervical degenerative disc disease. J Transl. Med. 2021 Jan 6;19:14.	PEEK cage coated with Ti and HA provided a higher fusion rate than uncoated PEEK cage at 3-month post-operation.
Johansson P. et al. Nanosized Hydroxyapatite Coating on PEEK Implants Enhances Early Bone Formation. Materials (Basel). 2015 Jun 25;8(7):3815-30.	The effect of HA-coating was concluded to be significant with respect to early bone formation, and HA-coated PEEK implants may represent a good material to serve as bone anchored clinical devices.
Ma R. et al. Osseointegration of nanohydroxyapatite- or nano-calcium silicate-incorporated PEEK bioactive composites. Int J Nanomedicine. 2016 Nov 14;11:6023-6033.	In vivo tests revealed that both n-CS/PEEK and n-HA/PEEK promoted osseointegration at the bone/implant interface compared to PEEK. These two PEEK biocomposites are promising materials for the preparation of orthopedic or craniofacial implants.
Mobbs RJ, et al. Biphasic calcium phosphate contained within a polyetheretherketone cage with and without plating for anterior cervical discectomy and fusion. Orthop Surg. 2012 Aug;4(3):156-65.	Biphasic calcium phosphate ceramic contained within a PEEK cage is an effective implant for use in anterior cervical surgery with high fusion rates and good clinical outcome.

Procedure Workflow

Kelyniam utilizes **CT-based DICOM** imaging to design each implant to the patient's defect anatomy and creates a defect model through 3D printing before CNC manufacturing the final implant.

Kelyniam's customized cranial and craniofacial implants are supported by a **CT scan protocol and IFU** available through the company's resource library and attached in the appendix to this document.

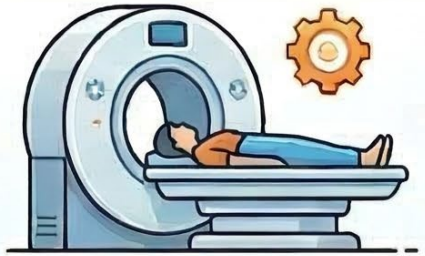


Scanning Parameters

Acquisition	Axial/Helical
Field of View (FOV)	20-25cm
Gantry Tilt	0~
Occlusal Plane	Correct position of the patient
Spacing	≤ 1.25mm
Slice Thickness	≤ 1.25mm
Algorithm	Standard (not bone or detail)
MA	170/>280
Time	1-second

KELYNIAM CRANIAL IMPLANT ORDERING PROCESS WORKFLOW

1. CT SCAN & DATA TRANSFER



CT Scan Protocol in ShareFile

↓

Contact Kelyniam: 800-280-8192 or info@kelyniam.com

Instructions for CT Scan Data Transfer

2. CT DATA REVIEW & COLLABORATION

Kelyniam Design Team Reviews Patient Data

↓

Issue identified? **No**

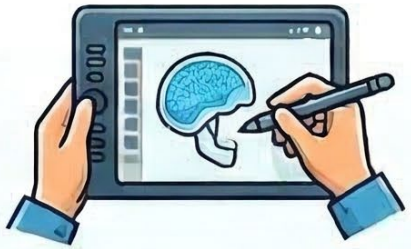
Yes

Surgeon / Rep Input Needed: Mark images, modify bone removal, specify defect

Marked images sent to info@kelyniam.com

Optional WebEx for Surgical Planning

3. DESIGN PROPOSAL & APPROVAL

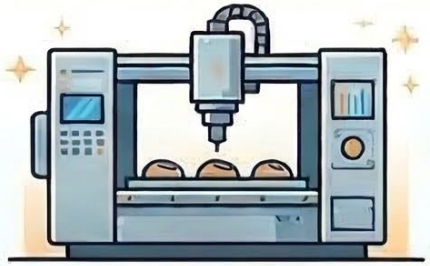


Proposal Sent to Surgeon for Electronic Signature

- **Urgent Case** (1-2 hr delivery of proposal)
- **Non-Urgent Case** (Review model of implant if requested)

Design Team creates true customized prosthetic for best outcome

4. FINAL PRODUCTION & DELIVERY



Design Finalized and Approved by Surgeon

Shipped same or next business day

24-Hour Turnaround Available for Urgent Cases across USA

Attention: Approval must be finalized by **11AM EST** for **24-Hour** Turnaround

Supply Chain

- All PEEK plates are manufactured in the USA
- Expedited delivery available within continental USA
  - 24-48 hours (see graphic on next slide)
  - For 24-hour delivery, approval must be received by 11 am EST
  - Subject to change due to inclement weather, etc.
- Excellent logistics: have delivered over 2,750 implants, urgent orders > 99% fulfillment
- Storage: Implants can be stored at ambient (room) temperature
- Implants are shipped non-sterile for sterilization at the end-user facility


24-HOUR DELIVERY FOR ALL CONTINENTAL USA LOCATIONS
FOR APPROVALS RECEIVED BY 11 AM EST
Leveraging our strategic hub in Canton, CT to reach the entire nation.
CANTON, CT
CHICAGO, IL
within 24 hours
DENVER, CO
within 24 hours
SAN FRANCISCO, CA
within 24 hours
LOS ANGELES, CA
within 24 hours
ATLANTA, GA
within 24 hours
MIAMI, FL
24 hours
DELIVERY TIME FROM CANTON, CT
ALL CONTINENTAL LOCATIONS
within 24 HOURS
RECIONAL AIR FREIGHT NETWORKS ENABLING EXPRESS DELIVERY

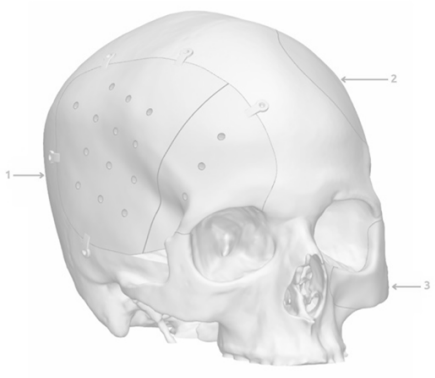
Kelyniam trained sales representatives are available for case coverage if required

Kelyniam can accommodate pilot program or trial (1-3 cases)

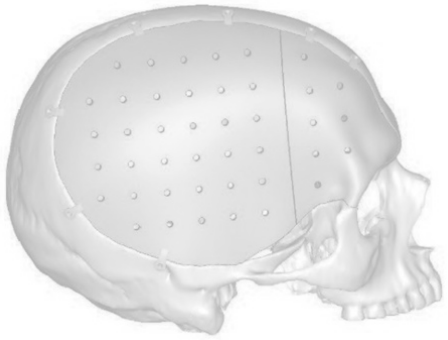
Onsite education and in-service can be provided upon request

Implementation Plan

Kelyniam Product Portfolio

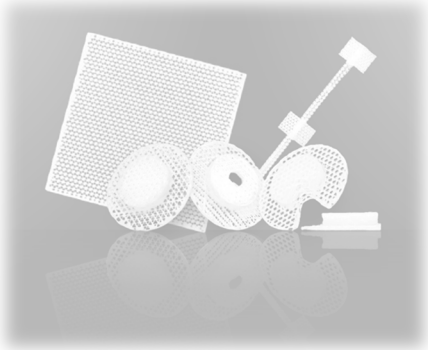


Customized Craniofacial Implant (CCI)
Customized Skull Implant (CSI)



Fusion Craniofacial Implant (FCI)
Fusion Skull Implant (FSI)

CustomizedBone™ Service
Patient Specific Hydroxyapatite Implant



Osteopore®
Regenerative Bone Scaffold

NEOS Surgery Cranial Loop™
Smart Cranial Fixation System

Product name:	**CustomizedBone Service**
Manufacturer:	**Fin-Ceramica Faenza S.p.A. (Italy)**
Product type:	**Patient-specific implantable medical device**
Service line:	**Neurosurgery**
Request type:	**New product approval**
Physician champion:	
Sales rep contact:	
Date of submission:	
Requested committee action:	

Executive Summary

- A formal letter of request by Dr. _____ has been submitted for approval of CustomizedBone patient-specific hydroxyapatite plates (Appendix B)
- CustomizedBone is made of a material that allows for a **porous and biomimetic structure** that provides osteoconductive properties that promote osteointegration and natural bone regrowth
- Backed by over 60 scientific publications, CustomizedBone has **demonstrated clinical safety** and efficacy including low infection rates versus other materials
- Using CT DICOM imaging for **high anatomical accuracy**, CustomizedBone ensures precise manufacturing and reliability
- Provides a **natural aesthetic result** enabling high level of patient satisfaction

Product Overview
CustomizedBone Service

- *Indicated to replace bony voids in the cranial and/or craniofacial skeleton (frontal bone including brow ridge).*
- **Hydroxyapatite** is ceramic bio-material with porous structure that mimics human bone
- **Interconnected pores** optimize housing of cells that promote bone regeneration
- High **biocompatibility** may mitigate post-op infections compared to other materials
- Addresses disadvantages of titanium, which is not biomimetic, osteoconductive, or radiolucent
- Unlike autologous bone, hydroxyapatite is not resorbed by the body
- Provides patients with **natural aesthetic** result
- **Radiolucent** making it MRI compatible
- > 8,000 implants in > 300 hospitals worldwide
- **Six multi-center publications** and 45+ peer-reviewed papers

Product Codes for Ordering
CustomizedBone Service

CustomizedBone	
Product Code	*Product Description*
DM-YYXXXX	CustomizedBone single prosthesis (1 primary implant + 1 backup implant)
DM-YYXXXX—DM-YYXXXX	CustomizedBone double prosthesis for large defects (1 + 1 primary implants and 1 + 1 backup implants)

Intended Use

CustomizedBone Service

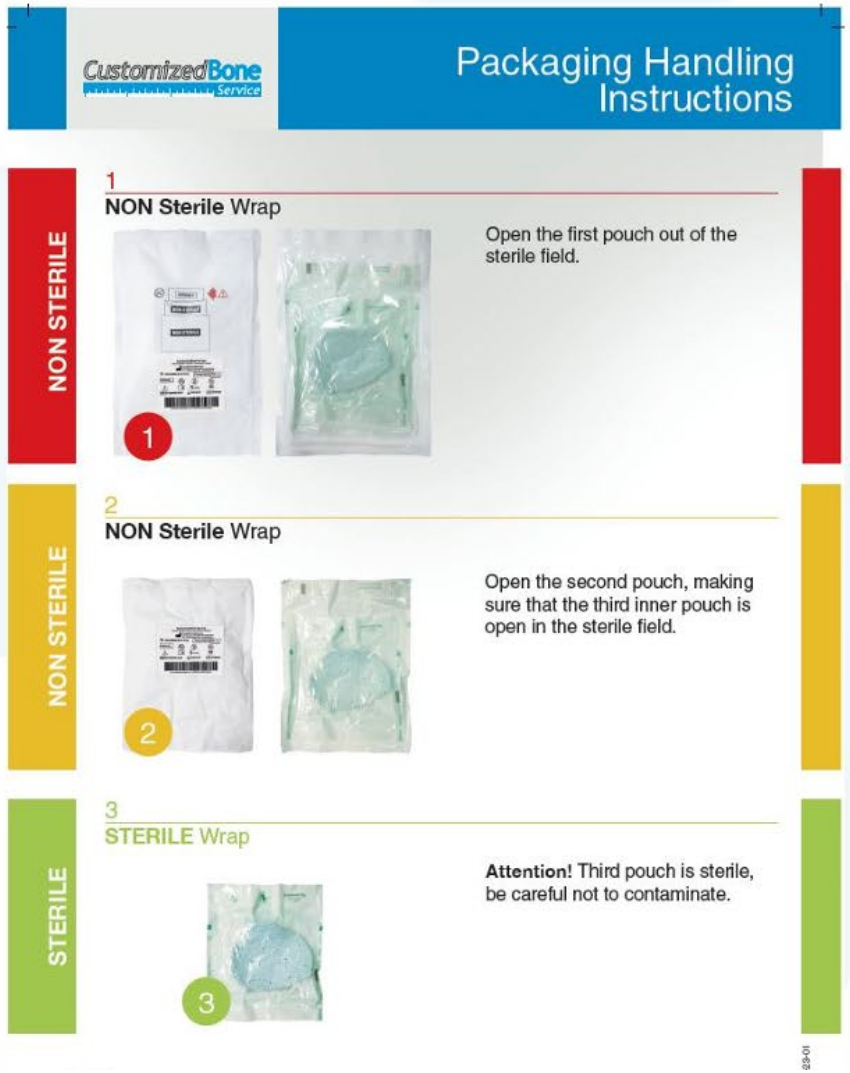
Patient specific hydroxyapatite implant

Biomimetic cranial reconstruction

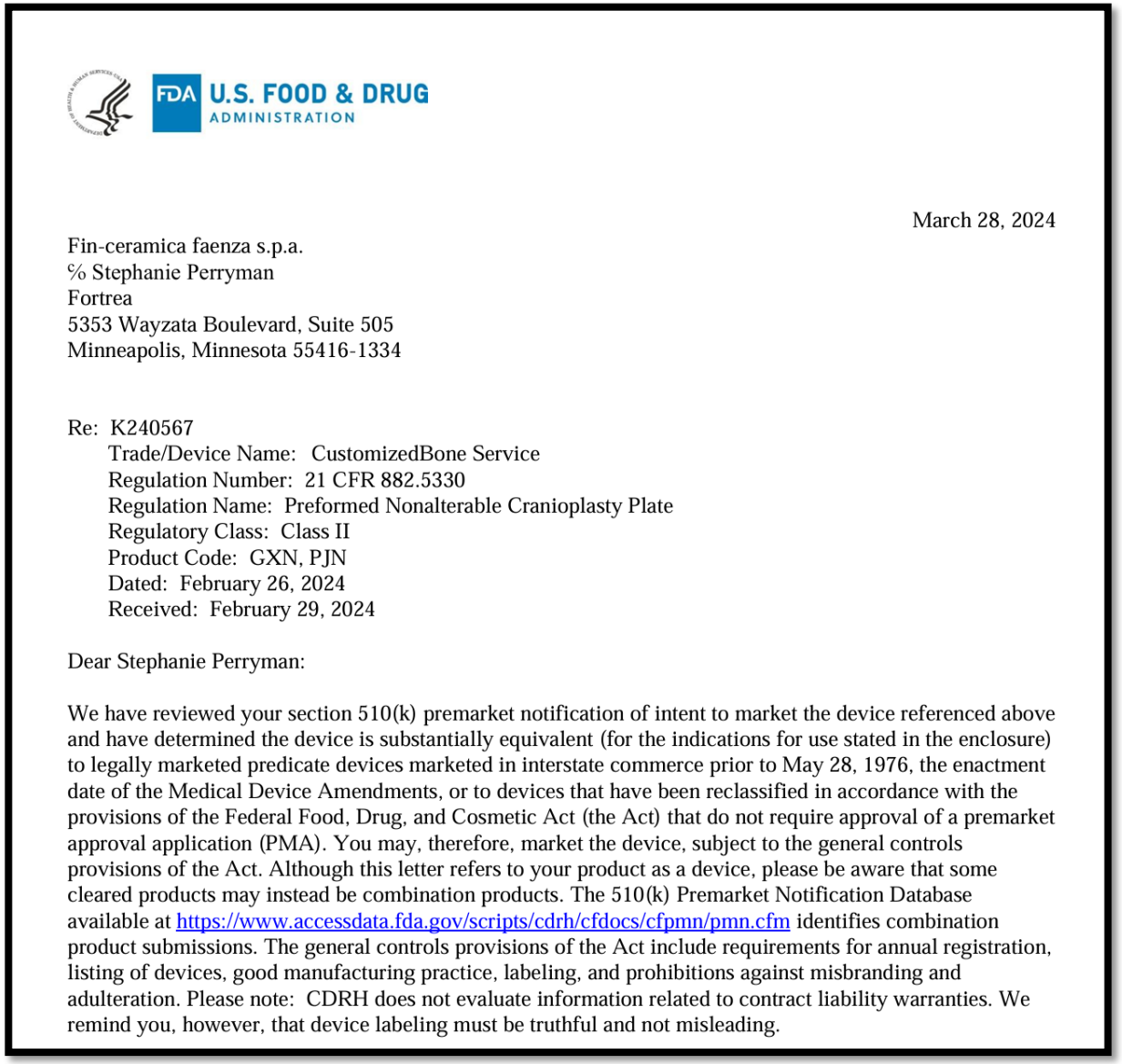
CustomizedBone Service (CustomizedBone) is intended to replace bony voids in the cranial and/or craniofacial skeleton (frontal bone including the brow ridge). This device is indicated for both adult and pediatric use (for children 7 years of age and above).
CustomizedBone implants are suitable for reconstructing cranial and/or craniofacial defects resulting from:

- trauma and vascular pathologies, either associated or non-associated to cranial decompression;
- removal of tumours;
- reabsorption of autologous bone;
- rejection of other prosthetic materials;
- congenital malformations.

Sterilization Instructions
Provided sterile with 2-year shelf-life



Regulatory / Quality



U.S. FOOD & DRUG ADMINISTRATION

March 28, 2024

Fin-ceramica faenza s.p.a.
% Stephanie Perryman
Fortrea
5353 Wayzata Boulevard, Suite 505
Minneapolis, Minnesota 55416-1334

Re: K240567
Trade/Device Name: CustomizedBone Service
Regulation Number: 21 CFR 882.5330
Regulation Name: Preformed Nonalterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: GXN, PJN
Dated: February 26, 2024
Received: February 29, 2024

Dear Stephanie Perryman:

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.

510(k) Clearance for:
CustomizedBone Service

Regulatory / Quality

ISO 13485:2016
ISO 9001:2015
Certifications for Fin-Ceramica SpA

DNV

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.: CS93822
Initial certification date: 27 May 2021
Valid: 30 May 2024 – 29 May 2027

This is to certify that the management system of
Fin-Ceramica Faenza S.p.A.
Via Ravegnana, 186 - 48018 Faenza (RA) - Italy
and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:
ISO 13485:2016

This certificate is valid for the following scope:
Design, manufacturing and placing on the market of non-active implantable medical devices resorbable or not, into ceramic or composite materials and related accessories. Technical design of custom-made medical devices, patient specific, for cranioplasty in porous hydroxyapatite, their production and sale.

Place and date:
Vimercate (MB), 15 March 2024

ACCREDIA

For the issuing office:
DNV - Business Assurance
Via Energy Park, 14, - 20871 Vimercate (MB) - Italy

Claudia Baroncini
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.
ACCREDITED UNIT: DNV Business Assurance Italy S.r.l., Via Energy Park, 14 - 20871 Vimercate (MB) - Italy - TEL: +39 039 68 99 905. www.dnv.it

DNV

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.: CS89116
Initial certification date: 20 April 1999 (by different Certification body)
Valid: 30 May 2024 – 29 May 2027

This is to certify that the management system of
Fin-Ceramica Faenza S.p.A.
Via Ravegnana, 186 - 48018 Faenza (RA) - Italy
and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:
ISO 9001:2015

This certificate is valid for the following scope:
Design, manufacturing and placing on the market of non-active implantable medical devices resorbable or not, into ceramic or composite materials and related accessories. Technical design of custom-made medical devices, patient specific, for cranioplasty in porous hydroxyapatite, their production and sale (IAF 12, 15, 35)

Place and date:
Vimercate (MB), 15 March 2024

ACCREDIA

For the issuing office:
DNV - Business Assurance
Via Energy Park, 14, - 20871 Vimercate (MB) - Italy

Claudia Baroncini
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.
ACCREDITED UNIT: DNV Business Assurance Italy S.r.l., Via Energy Park, 14 - 20871 Vimercate (MB) - Italy - TEL: +39 039 68 99 905. www.dnv.it

With more than 60 scientific papers published, CustomizedBone offers demonstrated durable long-term outcomes, reliable osteointegration, and low incidence of infection.

Citation	Finding
Zaed, et al. Cranioplasty infectionin porous hydroxyapatite: potential antibacterial properties. J ApplBiomaterFunctMater.2025;23:1–9.	Analyzing the growth trend of viable microorganisms under dynamic contact conditions it can be seen that porous hydroxyapatite cranioplasty appears to inhibit exponential growth by inducing bacterial stasis.
Zaccaria, et al. Hydroxyapatite ceramic implants for cranioplasty in children: a single center experience. Child's Nervous System Journal. 2017. 33(2):343-348.	Excellent osteointegration, with ~100% integration in the majority of patient and up to 4 years of FU. Porous HA supports osteoblast migration and bone formation. No major complications reported in the case series terms and excellent aesthetic outcomes.
Sprio, et al. Osteointegration in cranial bone reconstruction: a goal to achieve. Journal of Applied Biomaterials & Functional Materials. 2016 Nov 2;14(4):e470-e476.	PHA scaffolds show strong osteoconductive and osteogenic properties. Extensive bone ingrowth within the scaffold structure, enabling true osteointegration. Biomimetic structure enables restoration of bone-like mechanical properties.
Mannella FC et al., Long-term follow-up of custom-made porous hydroxyapatite cranioplasties: analysis of infections in adult and pediatric patients. J ClinMed.2024;13(4):1133.	687 patients, multicenter European study, mean follow up 25.6 months. Overall infection rate: 6% (main complication). Explantation rate: 4.4%. Bifrontal decompression = higher infection risk (12.5% vs 5.1%), independent predictor. No significant association with initial pathology or first- vs second-line surgery.

With more than 60 scientific papers published, CustomizedBone offers demonstrated durable long-term outcomes, reliable osteointegration, and low incidence of infection.

Citation	Finding
F. Faedo, et al. Infection rates following custom-made cranioplasty using heterologous materials: insights from a systematic review on 3260 patients with a focus on follow up length. Neurosurgical Review. 2025 Sep 19;48(1):657.	CustomizedBone is the cranioplasty device with the highest number of published patients, long-term follow-up and quality of studies. This review reports CustomizedBone to have the lowest infection rates among the cranioplasty materials.
R. Carbonaro, et al. Cranioplasty with porous hydroxyapatite custom made implants: a multidisciplinary approach of neurosurgeon and plastics surgeons to improve surgical technique and clinical outcome. Journal of Craniofacial Surgery. 2024 Jul-Aug;36(5):1470-1475.	Outcomes strongly depend on surgical technique and soft tissue management. Multi-disciplinary approach improves results. Complication rate: 7.8%; explant: 3.9%. Infection prevention relies on antibiotic prophylaxis and implant preparation.

CT Scan Guidelines

« Use a 3D scanning routine with high resolution images as comparable to image guided surgery, stereotactic planning, or other 3D applications. The CT Scan must encompass the defect with at least 2 cm above and 2 cm below to spare.

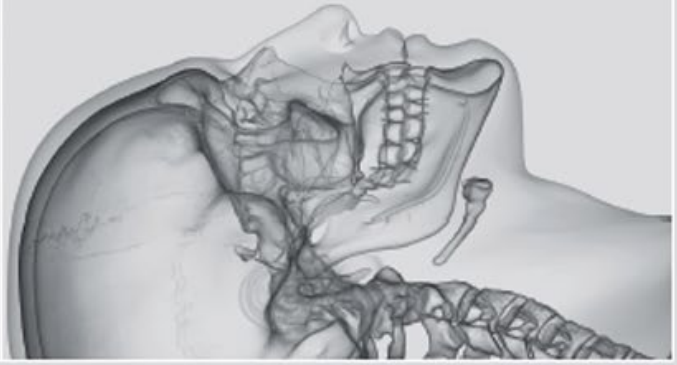
« Not Acceptable: images acquired with gantry tilt and then post-processed to reorient images (i.e. "take out" tilt).

« Image artifact caused by metallic implants can obscure anatomy of interest. Please take steps to minimize artifact from the presence of metal. It is useful to position the patient so that the occlusal plane is parallel to the image plane. This can help to limit artifact from metallic dental restorations to the region around the teeth.

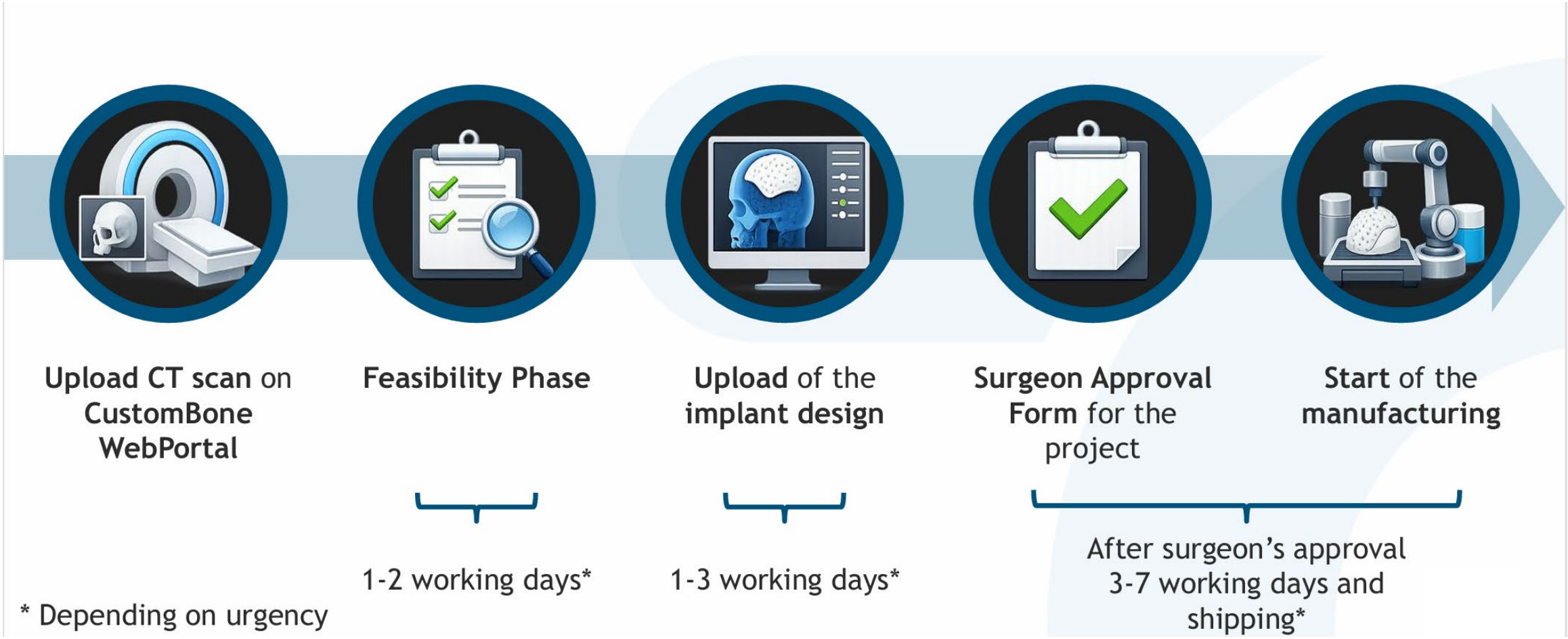
« For a correct processing of the 3D project, in case of cerebral tumor, in addition to CT Scan, please also provide MRI screening, if available.

We understand concerns for your patients about keeping the radiation dose as low as reasonably achievable, therefore, please apply these guidelines as appropriate to your patients.

	CT Scan Parameters
Slice Thickness	MAX 2 mm
Scan Spacing	MAX 2 mm (adjacent or overllaped)
Number of Slice	MIN 60 slices
Field of View	As small as possible, but to include entire skull
Algorithm	Use a proper image reconstruction algorithm to get sharp images
Slide Definition	at least 512x512 pixel
Gantry Tilt	0° (if possible) no more than 30°
Age of Scans	- Scans ≤3 months for patients from 2 years to less than 7 years - Scans ≤6 months for patients from 7 years to less than 12 years
File Type	DICOM (NOT fragmented or zipped)
Series	Preferred: Original/Primary/Axial (no recon, reformat or post process data)

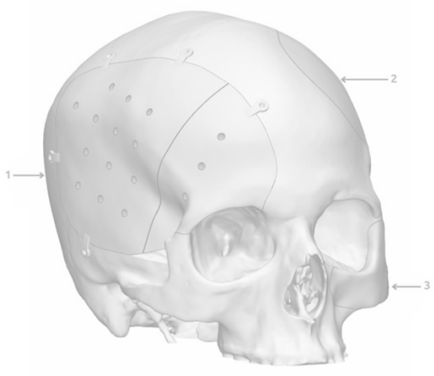


CustomizedBone Workflow
1-2 weeks Turnaround Time

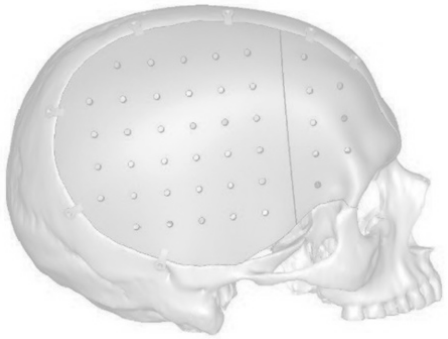


Made in Italy

Kelyniam Product Portfolio

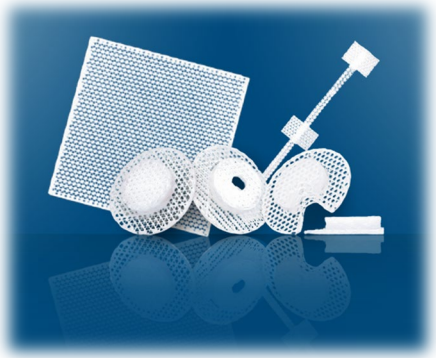


Customized Craniofacial Implant (CCI)
Customized Skull Implant (CSI)



Fusion Craniofacial Implant (FCI)
Fusion Skull Implant (FSI)

CustomizedBone™ Service
Patient Specific Hydroxyapatite Implant



Osteopore®
Regenerative Bone Scaffold

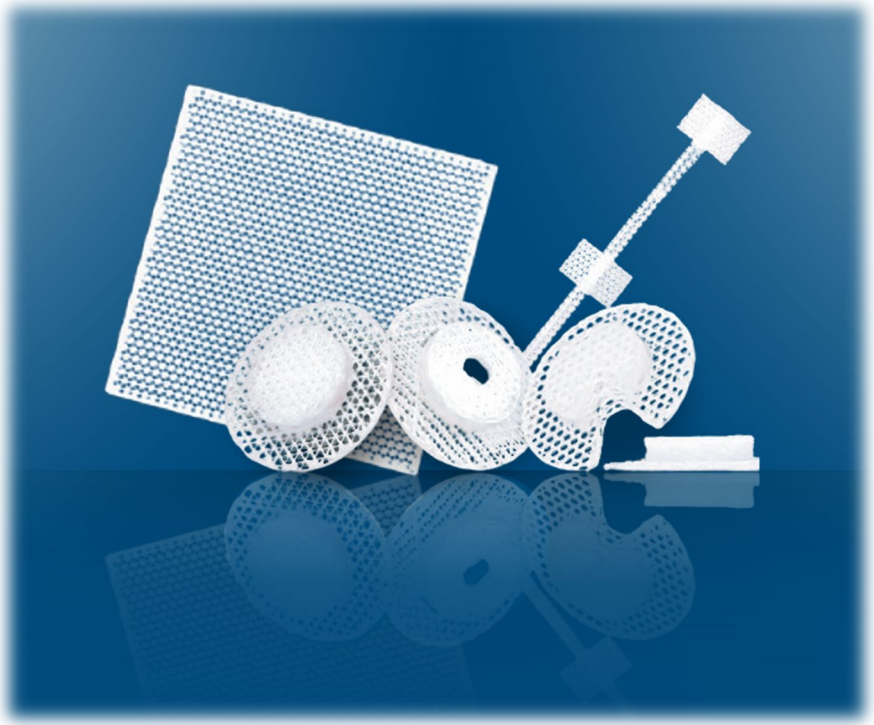
NEOS Surgery Cranial Loop™
Smart Cranial Fixation System

Product name:	**Osteopore Regenerative Bone Scaffold**
Manufacturer:	**Osteopore International Pte Ltd (Singapore)**
Product type:	**Bone void filler for Burr Holes and Craniotomies**
Service line:	**Neurosurgery**
Request type:	**New product approval**
Physician champion:	
Sales rep contact:	
Date of submission:	
Requested committee action:	

Executive Summary

- A formal letter of request by Dr. _____ has been submitted for approval of Osteopore's line of bone void filler products (Appendix C)
- Osteopore is a **bioresorbable** technology that promotes natural bone healing for use in Burr holes and craniotomies
- Scaffolds are made from PCL (polycaprolactone), a bioresorbable polymer that slowly **resorbs over 18–24 months**
- Unique interconnected porous structure **mimics natural trabecular bone**, facilitating rapid vascularization and bone ingrowth
- Off-the-shelf scaffolds are highly malleable, can easily **be trimmed or shaped in the OR**, allowing for precise anatomical fit without need for expensive custom-made implants
- May provide a more **aesthetic and comfortable** experience for patients
- Backed by over **10 years of clinical data**

Product Overview
Osteopore



- *Intended for use in the repair of neurosurgical burr holes, craniotomy cuts and other cranial defects.*
- Design **mimics cancellous bone** to promote vascularization and healing
- **First FDA clearance** for 3D printed bone device for use in craniofacial reconstruction
- Bone scaffold creates environment for **tissue and vascular ingrowth**
- Made of biodegradable polymer, **polycaprolactone** (PCL)
- Maintains **mechanical integrity** during healing process
- Implant **fully resorbs** over 24 months
- Designed to **minimize adverse** host-implant and inflammatory reactions
- Filling craniotomy gaps can result in **improved cosmesis**, reduced pain, and increased patient satisfaction
- **Over 90,000 implants** as of August 2023

Product Codes for Ordering
Osteopore Burr Hole Covers

Osteoplug Burr Hole Cover PC 22	
*Product Code**	*Product Description*
PC 22 (11, 11, 4)	Burr Hole Cover
PC 22 (13, 13, 4)	Burr Hole Cover
PC 22 (14, 14, 4)	Burr Hole Cover
PC 22 (15, 15, 4)	Burr Hole Cover

Osteoplug Burr Hole Cover PC 23	
*Product Code**	*Product Description*
PC 23 (11, 11, 4)	Burr Hole Cover SDH Drainage
PC 23 (13, 13, 4)	Burr Hole Cover SDH Drainage
PC 23 (14, 14, 4)	Burr Hole Cover SDH Drainage
PC 23 (15, 15, 4)	Burr Hole Cover SDH Drainage

Osteoplug Burr Hole Cover PC 24	
*Product Code**	*Product Description*
PC 24 (11, 11, 4)	Burr Hole Cover CSF Shunting
PC 24 (13, 13, 4)	Burr Hole Cover CSF Shunting
PC 24 (14, 14, 4)	Burr Hole Cover CSF Shunting
PC 24 (15, 15, 4)	Burr Hole Cover CSF Shunting

* (length, breadth, thickness) in mm

Product Codes for Ordering

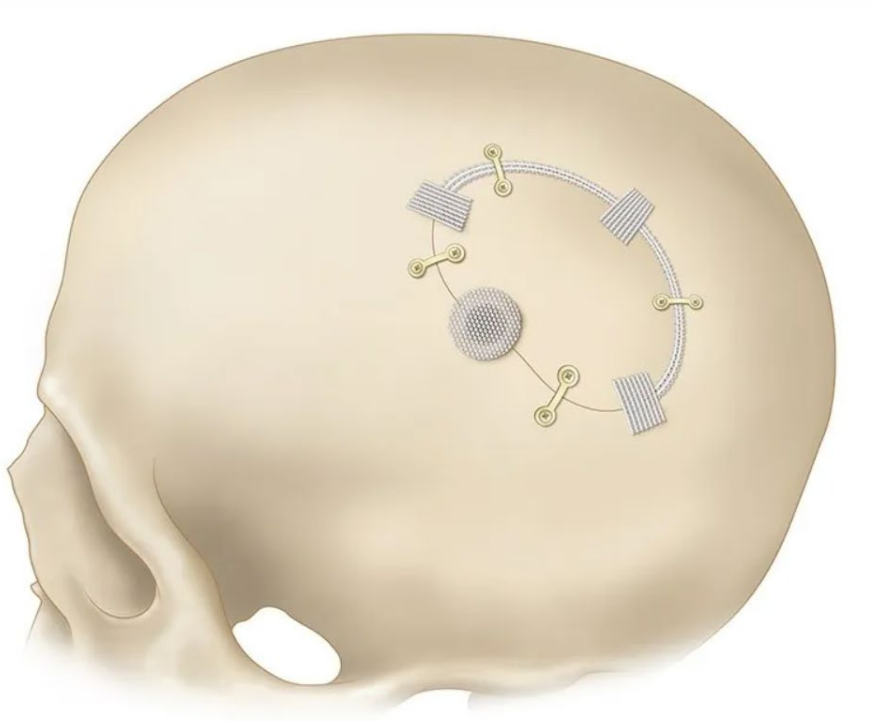
Osteopore Strip and Mesh

Osteostrip PC 17	
*Product Code**	*Product Description*
PC 17 (100, 2, 4)	Osteostrip for Craniotomy
PC 17 (100, 3.5, 4)	Osteostrip for Craniotomy

Osteomesh PC 11	
*Product Code**	*Product Description*
PC 11 (50, 50, 1)	Osteomesh
PC 11 (50, 50, 1.25)	Osteomesh
PC 11 (50, 50, 2)	Osteomesh

* (length, breadth, thickness) in mm

Intended Use



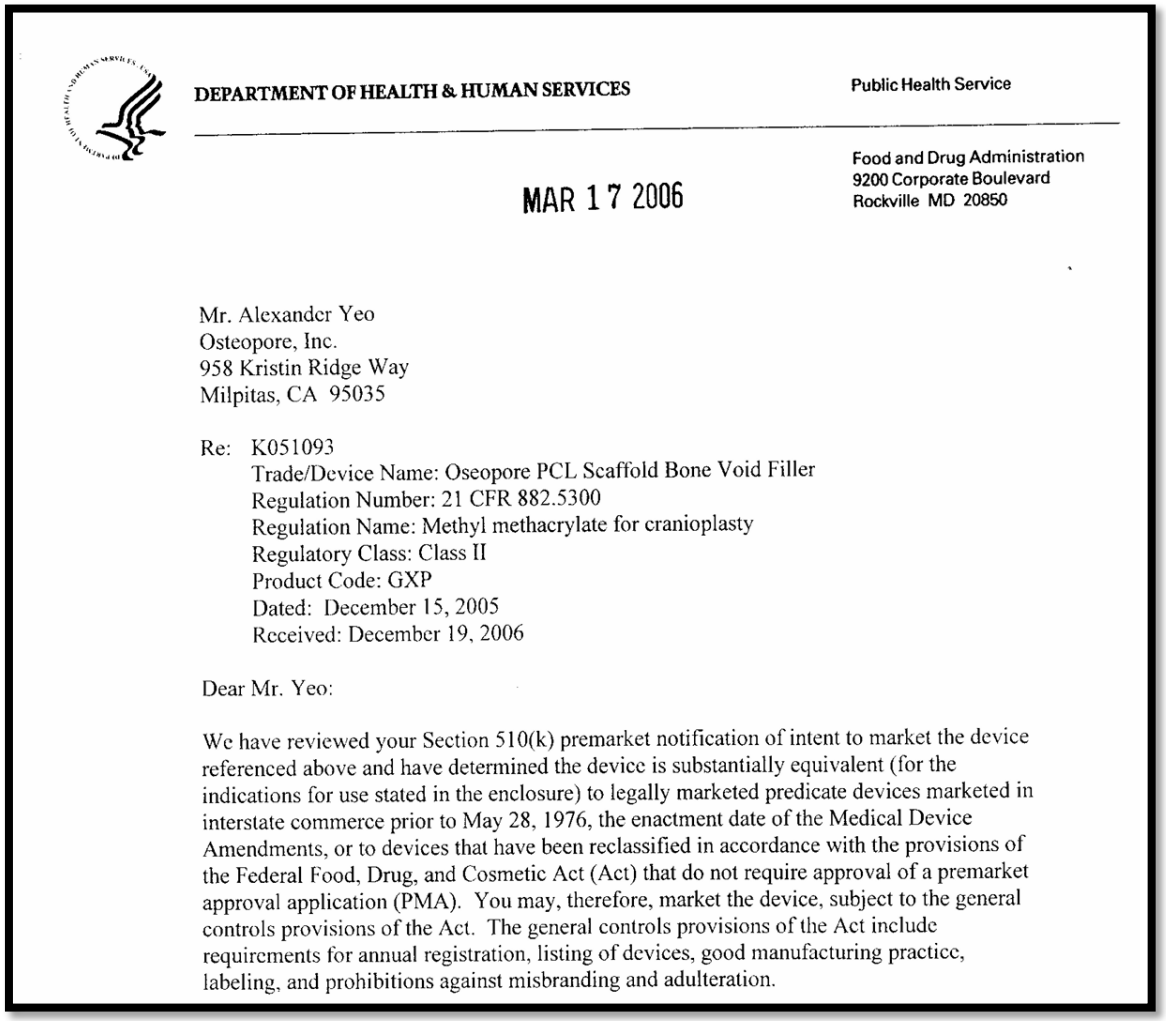
INSTRUCTIONS FOR USE
INTENDED USE / INDICATIONS
Osteopore® devices are intended for use in the repair of neurosurgical burr holes, craniotomy cuts, and other cranial defects. They are also for use in the augmentation or restoration of bony contour in the craniofacial skeleton. The shape of the device conforms to the defect, thus maximizing direct contact with viable host bone. The device is made of polycaprolactone which will degrade and resorb fully in vivo by hydrolysis into which it is then metabolized by the body, over a period of 18-24 months. This device does not contain radioactive substances and is safe for use with MRI.

Sterilization Instructions
Provided sterile

PREPARATION FOR USE

1. The device is provided in STERILE foil packaging.
2. Using aseptic technique, remove the device from foil packaging.
3. Place the device in the sterile field. It should only reside in sterile environment once removed from packaging.
4. If bone wax or gel foam is used, it should be removed from the bone interface prior to the administration of the material.

Regulatory / Quality



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2006

Mr. Alexander Yeo
Osteopore, Inc.
958 Kristin Ridge Way
Milpitas, CA 95035

Re: K051093
Trade/Device Name: Oseopore PCL Scaffold Bone Void Filler
Regulation Number: 21 CFR 882.5300
Regulation Name: Methyl methacrylate for cranioplasty
Regulatory Class: Class II
Product Code: GXP
Dated: December 15, 2005
Received: December 19, 2006

Dear Mr. Yeo:

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. 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.

510(k) Clearance for:
Osteopore PCL Scaffold Bone Void Filler

Regulatory / Quality

Certificate

Quality Management System
EN ISO 13485:2016
EN ISO 13485:2016/AC:2018
EN ISO 13485:2016/A11:2021

Registration No.: SX 2068842-1

Certificate Holder: Osteopore International Pte Ltd
2 Tukang Innovation Grove
#09-06 JTC MedTech Hub
Singapore 618305
Singapore

Scope: Design and Development, Manufacture and Distribution of Bioresorbable Bone Matrix Implant and Bioresorbable Custom-Made Devices for Bone Repair and Restoration.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 160108764-21
Effective date: 2025-08-04
Expiry date: 2028-08-03
Issue date: 2025-05-07
Replaces certificate SX 2068842-1 issued 2024-11-15

Furukawa Ryo

Ryo Furukawa
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on https://www.certipedia.com

1 / 1

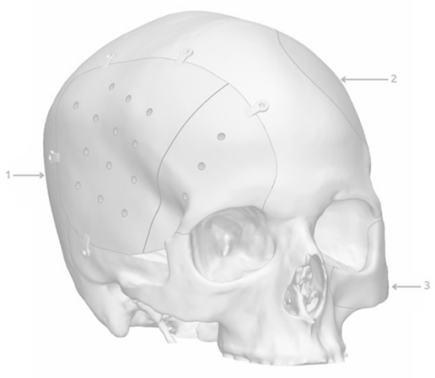
DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

TÜVRheinland® Precisely Right.

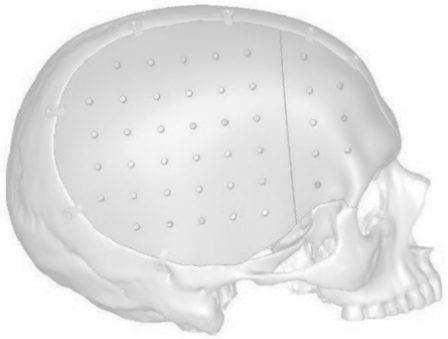
ISO 13485:2016
Certifications for Osteopore

Citation	Finding
Yang M et al. Cranial reconstruction using a polycaprolactone implant after burr hole trephination. Journal of 3D Printing Medicine 2020; 4:9-16.	In 174 patients with Osteopore burr hole cover from 2006-2015, demonstrated safety in use for craniotomy burr hole reconstruction.
Low SW et al. Use of Osteoplug polycaprolactone implants as novel burr-hole covers. Singapore Med J 2009; 50(8): 777-780.	12 patients with chronic subdural hematomas received Osteopore burr hole covers with a 16 month mean follow-up, showing good medium-term results, no adverse events, and excellent cosmesis.
Schantz JT et al. Cranioplasty after trephination using a novel biodegradable burr hole cover: technical case report. Neurosurgery 58[ONS Suppl 1]:ONS-176, 2006.	Over 12 months, patient shows increasing bone formation as seen on follow-up CT scans at 3 months, 6 months, and 12 months.
Toh EMS et el. Clinical outcomes of 3D-printed bioresorbable scaffolds for bone tissue engineering—a pilot study on 126 patients for burr hole covers in subdural hematoma. Biomedicines 2022, 10, 2702.	54 patients received Osteopore burr hole cover with good cosmetic outcomes. Authors conclude data support the device made of polycaprolactone as suitable adjuncts to burr hole craniotomy.

Kelyniam Product Portfolio

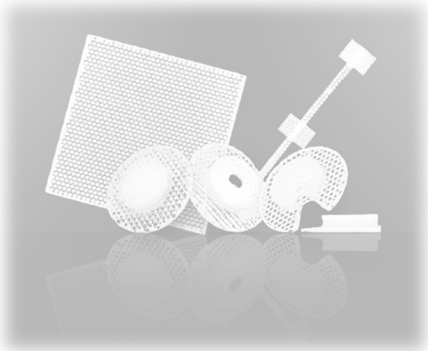


Customized Craniofacial Implant (CCI)
Customized Skull Implant (CSI)



Fusion Craniofacial Implant (FCI)
Fusion Skull Implant (FSI)

CustomizedBone™ Service
Patient Specific Hydroxyapatite Implant



Osteopore®
Regenerative Bone Scaffold

NEOS Surgery Cranial Loop™
Smart Cranial Fixation System

Product name:	**Cranial Loop Fixation System**
Manufacturer:	**Neos Surgery S.L. (Spain)**
Product type:	**Cranial Bone Fixation System**
Service line:	**Neurosurgery**
Request type:	**New product approval**
Physician champion:	
Sales rep contact:	
Date of submission:	
Requested committee action:	

Executive Summary

- A formal letter of request by Dr. _____ has been submitted for approval of Cranial Loop's bone fixation system (Appendix D)
- Cranial Loop is an innovative, non-metallic, suture-like fixation system designed for **fast and secure reattachment** of cranial bone flaps.
- Replaces traditional titanium plates and screws with **high-strength PEEK** (Polyether ether ketone) solution
- Unique "pull and tighten" mechanism allows for **fixation of standard bone flap in less than a minute** without use of specialized instruments
- Non-metallic PEEK-OPTIMA™ construction **eliminates metallic artifacts** in CT and MRI scans
- Sterile, off-the-shelf system **simplifies hospital logistics** by reducing need for instrument sterilization, specialized tray management, and related overhead costs

Product Overview
Cranial Loop

- *Intended for cranial bone fixation. Cranial Loop's function is to fix the bone flap in its anatomical position following a craniotomy*
- **Fast Fixation:** Reattach standard bone flap in less than one minute without specialized tools
- **Artifact-Free Imaging:** PEEK-OPTIMA™ material eliminates CT and MRI artifacts
- "Pull and tighten" mechanism **removes need for additional instruments** like drills, screws, or power tools
- Low-profile design adapts to bone curvature to optimize **patient comfort**
- Engineered to provide **bone flap stability** equivalent to traditional metallic plating systems
- Single-use sterile packaging simplifies tray management and **eliminates hospital sterilization costs**
- Non-metallic PEEK is a **biocompatible** material frequently used in medical implants with proven durability

Product Codes for Ordering

Cranial Loop

Cranial Loop SKUs	
Product Code	*Product Description*
FC050000	Osteotomy Line Device 12 mm
FC050100	Osteotomy Line Device 16 mm
FC050200	Burr Hole Device 22 mm

- Osteotomy line device
- 12 mm diameter

- Osteotomy line device
- 16 mm diameter

- Burr hole device
- 22 mm diameter

Intended Use

INSTRUCTIONS FOR USE
INTENDED USE / INDICATIONS
The Cranial LOOP Cranial Bone Fixation Systems: Cranial LOOP, Cranial LOOP (L) and Cranial LOOP (XL), are long-term implantable devices indicated for post-craniotomy bone flap fixation.

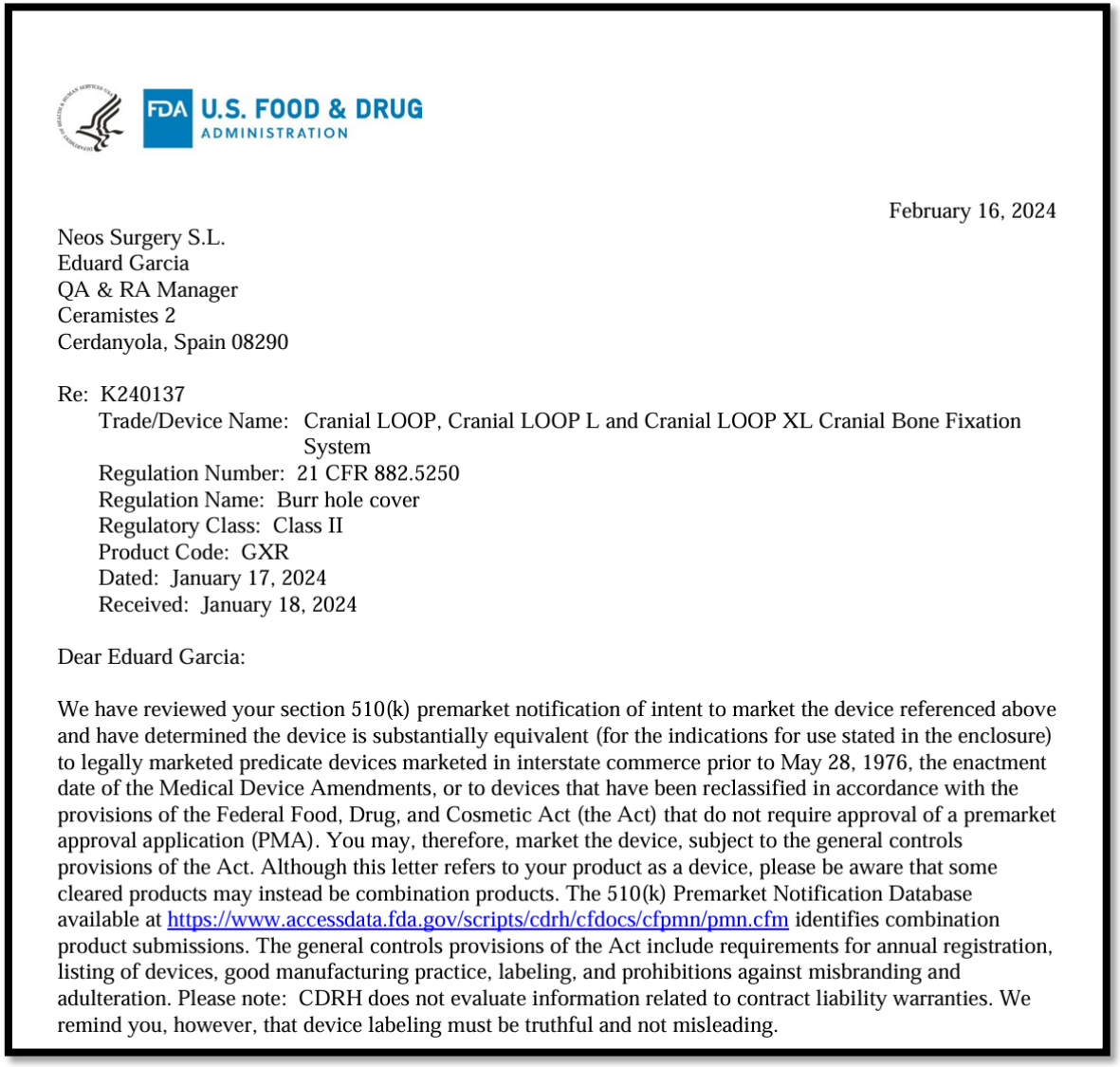
In cranial bone fixation procedures, the Cranial LOOP (FC050000) and Cranial LOOP (L) (FC050100) are for use within the osteotomy line (calvarial gap) while the Cranial LOOP (XL) (FC050200) is to be used for covering a standard 14 mm cranial burr hole only.

Sterilization Instructions
Provided sterile

Cranial LOOP is intended for single use and should never be re-used. Re-using Cranial LOOP may cause malfunction, breakage or infection.

Provided sterile. Sterilized by radiation. MR safe. Use only if sterile conditions specified in the label are guaranteed. Do not use if the package is opened or damaged.

Regulatory / Quality



U.S. FOOD & DRUG ADMINISTRATION

February 16, 2024

Neos Surgery S.L.
Eduard Garcia
QA & RA Manager
Ceramistes 2
Cerdanyola, Spain 08290

Re: K240137
Trade/Device Name: Cranial LOOP, Cranial LOOP L and Cranial LOOP XL Cranial Bone Fixation System
Regulation Number: 21 CFR 882.5250
Regulation Name: Burr hole cover
Regulatory Class: Class II
Product Code: GXR
Dated: January 17, 2024
Received: January 18, 2024

Dear Eduard Garcia:

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.

510(k) Clearance for:
Cranial LOOP

Regulatory / Quality

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 057431 0014 Rev. 03

Holder of Certificate: **Neos Surgery S.L.**
C/ Ceramistes 2
08290 Cerdanyola del Valles (Barcelona)
SPAIN

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Scope of Certificate: **Design and development, production, sales and distribution of sterile non-active orthopaedic implants**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 057431 0014 Rev. 03

Report No.: 713298714

Valid from: 2024-01-01
Valid until: 2026-12-31

Date, 2023-12-27

Christoph Dicks
Head of Certification/Notified Body

Page 1 of 2
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Certifications for Cranial Loop

Citation	Finding
C. Asencio et al. Long-Term Safety and Performance of a Polymeric Clamp-like Cranial Fixation System. World Neurosurg. 2019 Jun:126:e758-e764. doi: 10.1016/j.wneu.2019.02.146. Epub 2019 Mar 7.	Cranial LOOP is a safe and reliable postoperative long-term cranial bone flap fixation system. This device can fix the bone flap after a wide range of craniotomy procedures, performed in multiple locations, and provides good bone flap alignment. Cranial LOOP does not interfere in patient follow-up through medical imaging.
Van Loock K. et al. Cranial Bone Flap Fixation using a New Device (Cranial LOOP). Minim Invasive Neurosurg. 2011 Jun;54(3):119-24. doi: 10.1055/s-0031-1283171. Epub 2011 Aug 23.	Cranial LOOP is fast, easy and safe to use bone flap fixation device with the main advantage being the absence of artifacts on postoperative CT or MR imaging and lack of cosmetic disadvantage.
Vilana FX et al. Comparison between PEEK and Titanium cranial fixation devices: load-bearing properties, artefacts in medical imaging and radiation shielding.	Non-metallic materials, such as polymers, ceramics and composites, can present advantages compared to metals in medical implants: tissue-friendly mechanical properties, less artefacts, etc. Cranial LOOP is an example of this trend, by achieving equivalent functionality with advantages in medical imaging.

APPENDIX A

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

Fusion Craniofacial Implant (FCI)
Fusion Skull Implant (FSI)

APPENDIX B

CustomizedBone Service

APPENDIX C

Osteopore Regenerative Bone Scaffold

APPENDIX D

Cranial Loop Fixation System