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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Adam D. Pierce -S
Digitally signed by Adam D. Pierce -S
Date: 2024.03.28 16:45:07 -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
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240567

Device Name

CustomizedBone Service

Indications for Use *(Describe)*

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.

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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510(k) Summary

Prepared on: 2024-03-27

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Fin-ceramica faenza s.p.a.
Applicant Address	Via Ravegnana 186 Faenza RA 48018 Italy
Applicant Contact Telephone	+39 0546 607311
Applicant Contact	Marina Monticelli
Applicant Contact Email	mmonticelli@finceramica.it
Correspondent Name	Fortrea
Correspondent Address	5353 Wayzata Boulevard, Suite 505 Minneapolis MN 55416-1334 United States
Correspondent Contact Telephone	612-476-4371
Correspondent Contact	Stephanie Perryman
Correspondent Contact Email	stephanie.perryman@fortrea.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	CustomizedBone Service
Common Name	Preformed nonalterable cranioplasty plate
Classification Name	Plate, Cranioplasty, Preformed, Non-Alterable
Regulation Number	882.5330
Product Code(s)	GXN, PJN

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K193547	CustomizedBone Service	GXN

Device Description Summary

21 CFR 807.92(a)(4)

Hydroxyapatite is contained in human bones in percentage close to 70% and is one of the most important elements of human bone structure. CustomizedBone Service patient specific implants for the reconstruction of cranial/craniofacial defects are made of porous bio-mimetic hydroxyapatite with a chemical composition and structure that resembles the mineral component of human bones. This biomaterial is highly porous with trabecular structure and is composed of pores with the following characteristics:

- macro-pores,
- interconnecting pores,
- micro-pores.

This material is biocompatible.

The implants are designed and produced by Fin-Ceramica Faenza according to the surgeon's specifications and based on the patient's CT scan data, obtained through a standardized protocol. During the pre-operative planning phase, the surgeon must approve the final

implant design. All the implants are accompanied by the patient's identification code.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use of the subject device remain the same as the predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

The design and materials of the implant remain the same as the predicate device. The only change between the subject device and predicate device is the introduction of an alternative fixation method (Cranial bone fixation clamp made of biocompatible PEEK OPTIMA™ - Cranial LOOP (L) manufactured by NEOS Surgery S.L. or equivalent). The new fixation method has been validated and the subject device can be considered substantially equivalent to the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The following tests were completed to validate the effectiveness of the CustomizedBone Service implantation with PEEK OPTIMA™ clamps:
• Stability verification of CustomizedBone Service stabilized with Cranial LOOP (L)
• Usability of an alternative method of fixation for CustomizedBone Service product

Based on the above testing, fixation of the CustomizedBone Service with PEEK OPTIMA™ clamps (Cranial LOOP (L) manufactured by NEOS Surgery S.L. or equivalent) has been validated and the subject device can be considered substantially equivalent to the predicate device.