October 28, 2022

Kontour(Xi'an) Medical Technology Co., Ltd.
% Joyce Yang
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1713A, 17th Floor, Block A, Zhongguan Times Square
Nanshan District
Shenzhen, Guangdong 518100, China

Re: K214109
Trade/Device Name: PEEK Patient Specific Cranial/Craniofacial Implant(PSCI)
Regulation Number: 21 CFR 882.5330
Regulation Name: Preformed Nonalterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: GXN
Dated: September 28, 2022
Received: September 29, 2022

Dear Joyce Yang:

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/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 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 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, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K214109

Device Name
PEEK Patient Specific Cranial/Craniofacial Implant (PSCI)

Indications for Use *(Describe)*
The PEEK Patient Specific Cranial/Craniofacial Implant (PSCI) is intended to replace bony voids in the cranial and/or craniofacial skeleton, excluding maxillofacial and /or oral regions.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date of Summary prepared: October 28, 2022

1. Submission Sponsor

Applicant Name	Kontour(Xi'an) Medical Technology Co., Ltd.
Address	No.6, Qinling Avenue, Caotang Technology Industries Base, Xi'an High-tech Zone, 710304 Xi'an, China
Contact person	Rongrong Cong
Phone	086-29-63364685
E-mail	cong_rongrong@kontmed.com

2. Submission correspondent

Name	Shenzhen Joyantech Consulting Co., Ltd
Address	1713A, 17th Floor, Block A, Zhongguan Times Square, Nanshan District, Shenzhen
Post Code	518000
Phone No.	+86-755-86069197
Contact Person	Joyce Yang
Email	joyce@cefda.com

3. Device Identification

Type of 510(k) submission:	Traditional
Trade Name:	PEEK Patient Specific Cranial/Craniofacial Implant(PSCI)
Model:	No specific model (Custom device)
Classification name:	Plate, Cranioplasty, Perfoemed, Non-alterable
Review Panel:	Neurology
Product Code:	GXN
Device Class:	II
Regulation Number:	21 CFR § 882.5330

4. Legally Marketed Predicate Device

Trade Name	Patient Contoured Implant - PEEK (PCI-PEEK)
Regulation number	21 CFR § 882.5330
Regulation class	II
Regulation name	Preformed nonalterable cranioplasty plate
510(k) Number	K151382
Product Code	GXN
Manufacturer	KLS-MARTIN L.P.

5. Device Description

The PEEK Patient Specific Cranial/Craniofacial Implants are designed individually for each patient to correct defects in cranial/facial bone, and fabricated using the patient' s CT imaging data. The implants are made of PEEK material which is medical grade material. The PSCI consists of PEEK bone plate, and it is fixated to native bone using previously cleared Bioplate Fixation System manufactured by Bioplate, Inc.

The PSCI is provided in non-sterile and must be sterilized before use in Health Care Facility.

6. Intended Use/ Indications for Use

The PEEK Patient Specific Cranial/Craniofacial Implant(PSCI) is intended to replace bony voids in the cranial and /or craniofacial skeleton, excluding maxillofacial and /or oral regions.

7. Technological characteristics Comparison

Table 1: General Comparison

.**Comparison item**	**Subject Device:** PEEK Patient Specific Cranial/Craniofacial Implant	**Predicate Device:** Patient Contoured Implant-PEEK (K151382)	**Comments**
Indication for Use	The PEEK Patient Specific Cranial/Craniofacial Implant(PSCI) is intended to replace bony voids in the cranial and /or craniofacial skeleton, excluding maxillofacial and /or oral regions.	The Patient Contoured Implant - PEEK (PCI-PEEK) is intended to replace bony voids in the cranial skeleton.	Same
Anatomical Sites	Cranial or Craniofacial	Cranial	Similar (Issue 1)
Material	PEEK	PEEK	Same
Style	Solid with holes	Solid or solid with holes	Same
Sterilization	Provided non-sterile (The PSCI is provided non-sterile and must be sterilized before use)	Provided Sterile (Gamma)	Different (Issue 2)
Design and manufacture	Customized device, designed and manufactured in accordance	Customized device, designed and manufactured in accordance	Same

.**Comparison item**	**Subject Device:** PEEK Patient Specific Cranial/Craniofacial Implant	**Predicate Device:** Patient Contoured Implant-PEEK (K151382)	**Comments**
	with patient's CT-scan data	with patient's CT-scan data	
Method of Fixation	Titanium Screws and Titanium Plates	Titanium Screws and Titanium Plates	Same
Where used (hospital, home, ambulance,etc.)	Health Care Facilities / Hospitals	Health Care Facilities / Hospitals	Same

Issue 1: The difference between a implant used to replace Cranial bone and a implant used to replace craniofacial bone is that the shape of the implant. The material of the implant and its contact with the human body are the same. So this difference would not raise new issue of safety or effectiveness.

Issue 2: The subject device is provided in non-sterile and must be sterilized before use in Health Care Facility. The sterilization has been validated. And many similar devices are also provided in this way, such as Patient Contoured Mesh - PEEK (K072707).

8. Summary of Non-clinical Testing

The biocompatibility evaluation for the PEEK Patient Specific Cranial/Craniofacial Implant (PSCI) was conducted in accordance with the 2020 FDA guidance document Use of International Standard ISO 10993-1 *"Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process."* and International Standard ISO 10993-1 *"Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process"* as recognized by FDA.

The evaluation tests of the PSCI contain:

- In Vitro Cytotoxicity Test
- Skin Sensitization Test
- Intracutaneous Reactivity Test
- Acute Systemic Test
- Material-mediated Pyrogens
- Bone Implantation Test

- Extractable Assessment

The LAL endotoxin testing demonstrates that the sterile PEEK implant conforms to the required ≤20 EU/device.

The Particle testing has been conducted in accordance with USP<788>.

Based on the intended use of the subject device, the performance evaluation for PEEK Patient Specific Cranial/Craniofacial Implant (PSCI) was conducted in compression, fitting, and fixation.

9. Brief discussion of clinical tests

No clinical tests were performed.

10. Conclusions

The subject device, PEEK Patient Specific Cranial/Craniofacial Implant has the same intended use, design, function, and is composed of the same material as the predicate device, Patient Contoured Implant-PEEK. The subject device differs from the predicate device in that it will be provided in non-sterile and must be sterilized before use in Health Care Facility. This difference does not raise new issues of safety or effectiveness. Based on the comparison and analysis above, the subject device is determined to be Substantially Equivalent (SE) to the predicate device.