July 29, 2026

CraniUS, LLC
Oxana Pantchenko
Regulatory Consultant
1700 Union Ave., Suite A1
Baltimore, Maryland 21211

Re: K261058
Trade/Device Name: CraniUS Plate
Regulation Number: 21 CFR 882.5320
Regulation Name: Preformed Alterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: GWO
Dated: July 2, 2026
Received: July 2, 2026

Dear Oxana Pantchenko:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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

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

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

Sincerely,

JULIA E. SLOCOMB -S

Digitally signed by JULIA E. SLOCOMB -S
Date: 2026.07.29 16:59:00 -04'00'

for Jaime Raben, Ph.D.
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.

510(k) Number *(if known)*
K261058

Device Name
CraniUS Plate

Indications for Use *(Describe)*
The CraniUS Plate is indicated for use to fill a bony void or defect areas in a cranial skeleton.

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.

510(k) Summary
Date Prepared: July 28, 2026

Manufacturer and 510(k) Owner
CraniUS, LLC
1700 Union Avenue, Suite A1
Baltimore, MD 21211
Official Contact: Bejan Darbandi, VP, Systems Engineering

Representative/Consultant
Oxana S. Pantchenko Ph.D.
(650)269-4915
Oxana@MedicalDeviceConsulting.US

Device Information
Name: CraniUS Plate
Regulation Number: 21 CFR 882.5320 - Preformed alterable cranioplasty plate
Class: II
Product Code: GWO – Plate, Cranioplasty, Preformed, Alterable
Medical Specialty: Neurology

Predicate/Device Identification
K182711 Customized Craniofacial Implant (CCI), Customized Skull Implant (CSI), Kelyniam Global Inc.

Device Description
The CraniUS Plate is indicated for use to fill a bony void or defect areas in a patient's specific cranial skeleton. The implant is attached to the bone using FDA cleared cranial fixation screws and plates. The device is machined from Polyether Ether Ketone (PEEK) material. The CraniUS Plate may contain convenience features requested by surgeons: perfusion / suture holes, cut-backs, through-holes, and/or an opening for an implantable reservoir. Implantable reservoirs are not included. The device is provided non-sterile. The CraniUS Plate is a prescription-only device.

Indications for Use
The CraniUS Plate is indicated for use to fill a bony void or defect areas in a cranial skeleton.

Comparison of Technological Characteristics
The CraniUS Plate has similar indications for use, technology, and material compared to the predicate device: K182711 Kelyniam Global Inc., Customized Skull Implant (CSI). More specifically, both implants are indicated to fill a bony void or defect area in a patient's specific cranial skeleton. Both implants are made from the same material and are contract manufactured by Kelyniam Global, Inc. Both devices are provided clean but not sterile. CraniUS Plate's implant size range and thickness are identical to the predicate device. CSI implants may have the following features: perfusion holes, integrated fixation system, temporal cutback, and multi-part implant. With the exclusion of the integrated fixation system and multi-part implant, the CraniUS Plate could have the same set of features, as well as an additional opening feature for an implantable reservoir. The feature consists of a central burr hole and a circular pattern of suture holes. Each hole has similar characteristics as those cleared in K182711. This feature will be offered as an additional customization option to be added to the implant per surgeon's request. While minor dimensional differences are present between the two devices, they do not alter the indications for use of the subject device. Minor dimensional differences along with successfully performed mechanical testing do not affect the safety and effectiveness of the subject device, nor do they raise any new or novel safety or effectiveness questions from those raised by the predicate device.

Please see the device comparison table for additional details.

	Subject Device	**Predicate**
Device Name	The CraniUS Plate	Customized Craniofacial Implant (CCI) and Customized Skull Implant (CSI)
510(k) clearance	-	K182711
Regulation	21 CFR 882.5320	21 CFR 882.5320
Product Class	II	II
Product Code	GWO	GWO
Indications for Use	The CraniUS Plate is indicated for use to fill a bony void or defect areas in a cranial skeleton.	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).
Material	Evonik Vestakeep i4	Invibio Inc. PEEK-Optima LT-1 and Evonik Vestakeep i4
Technical Specification	Customized skull implant	Plate - Custom sized to each patient using CT scan data
Sterilization	Provided non-sterile	Provided non-sterile
Features	Perfusion/suture holes, temporal cutback, openings for an implantable reservoir.	Perfusion holes, integrated fixation system, temporal cutback, multi-part implant.

Summary of Non-Clinical Testing:

<u>Biocompatibility Testing:</u>

The CraniUS Plate is categorized as a long term (> 30days) implant in direct contact with tissue/ bone, neural tissue and CSF. The following biocompatibility endpoints were assessed on the final, finished, sterilized device and it was determined that no additional testing was needed: cytotoxicity, sensitization, irritation or intracutaneous reactivity, acute systemic toxicity, material-mediated pyrogenicity, subchronic systemic toxicity, chronic systemic toxicity, hemocompatibility (indirect hemolysis test), genotoxicity, neurotoxicity, implantation, and carcinogenicity.

<u>Cleaning and Sterilization Testing:</u>

Sterilization validation test was assessed on the final, finished, sterilized device and it was concluded that the subject device had no impact on the predicate sterilization validation.

The Bacterial Endotoxins Test was successfully completed. This testing was conducted in accordance with the following regulatory documents: ANSI/AAMI ST72:2019, ISO 11737-3:2023, USP <161>, USP <85>, EP 2.6.14, and JP 4.01.

<u>Mechanical Testing:</u>

There is no industry accepted standard governing mechanical testing for non-load bearing implantable cranioplasty plates. A mechanical testing verification protocol was developed where the performance characteristics were compared to those of the predicate device. All mechanical testing was conducted at a 3rd party accredited testing laboratory.

<u>MR Safety:</u>

The CraniUS Plate is electrically nonconductive or a nonmagnetic item and poses no known hazards in all MR environments. The CraniUS Plate implants are MR Safe.

Summary of Clinical Testing:

Clinical testing was determined not applicable for the CraniUS Plate.

Conclusion

The subject device utilizes the same intended use, same material composition, and similar technological characteristics as the predicate device such that the CraniUS Plate does not raise new issues of safety or effectiveness when compared to the predicate device. The non-clinical laboratory data indicate that the subject device is as safe, as effective, and performs as well as the predicate device and support a finding of substantial equivalence.