June 18, 2026

The Surgeon General, Department of the Army (TSG-DA)
India El
Regulatory Affairs Scientist
DHA R&D - Medical Research and Development Command; ATTN:
FCMR-ORA, 1541 Porter Street
Fort Detrick, Maryland 21702-9247

Re: K253116
Trade/Device Name: 3D MAC Titanium Cranial Plate (TCP) System
Regulation Number: 21 CFR 882.5330
Regulation Name: Preformed Nonalterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: GXN
Dated: May 18, 2026
Received: May 19, 2026

Dear India El:

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: 2026.06.18 10:05:40 -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)*
K253116

Device Name
3D MAC Titanium Cranial Plate (TCP) System

Indications for Use *(Describe)*
The 3D MAC Titanium Cranial Plate (TCP) System is a patient-specific device that is indicated for use to replace bony voids in the cranial and/or craniofacial skeleton (e.g., frontal bone, temporal bone, occipital bone, nasal bone, parietal bone, supraorbital process, lacrimal bone, zygomatic bone, sphenoid bone, ethmoid process, vomer).

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.

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510(k) Summary

Contact Information

Applicant Information:	The Surgeon General, Department of the Army (TSG-DA)
Applicant Address:	Defense Health Agency Research & Development; ATTN: FCMR-ORA 1541 Porter Street Fort Detrick, MD 21702-9247
Primary Contact:	India El, MS, BS Regulatory Affairs Scientist Office of Regulated Activities Defense Health Agency Research & Development 301-619-8296 india.o.el.ctr@health.mil
Alternate Contact:	Peter Liacouras, PhD Director of Services, 3D Medical Applications Center 301-295-8592 peter.c.liacouras.civ@health.mil
Date Prepared:	June 16, 2026

Device Information

Trade Name:	3D MAC Titanium Cranial Plate System
Common Name:	Cranial Plate
Classification Name:	Preformed nonalterable cranioplasty plate
Classification:	21 CFR 882.5330
Product Code:	GXN

Predicate Device Information

Predicate Device Name:	BioArchitects Patient Specific Cranial/Craniofacial Plate (K151692)
Classification:	21 CFR 882.5330
Product Code:	GXN

Device Description

The 3D MAC Titanium Cranial Plate (TCP) System includes the TCP Implant and TCP Skull Anatomical Model (SAM). The TCP System is indicated for use in cranioplasty surgery to replace bony voids in the cranial and/or craniofacial skeleton and is patient-specific. The TCP Implant replaces the bony void in the skull and the SAM is provided as a surgical reference tool to aid in the fitting and positioning of the TCP Implant. The TCP Implant is manufactured on an electron beam melting (EBM) 3D printer out of Ti6Al4V titanium alloy powder. The SAM is printed on a stereolithography (SLA) 3D printer out of clear photopolymer resin. The TCP Implant is an implantable, non-load bearing, and non-alterable medical device. The TCP Implant

is individually-sized and designed specifically for each patient case to replace the bony void of the patient's cranium. The TCP Implant is initially designed from a 3D Model of the SAM. The SAM is designed from the patient's CT scan and utilized as a fit check for the TCP Implant.

Indications for Use Statement

The 3D MAC Titanium Cranial Plate (TCP) System is a patient-specific device that is indicated for use to replace bony voids in the cranial and/or craniofacial skeleton (e.g., frontal bone, temporal bone, occipital bone, nasal bone, parietal bone, supraorbital process, lacrimal bone, zygomatic bone, sphenoid bone, ethmoid process, vomer).

Predicate Device Comparison

	Subject Device (K253116) 3D MAC Patient-Specific TCP	**Predicate Device (K151692) BioArchitects Patient-Specific Cranial/Craniofacial Plate**
Classification	II	II
Regulation	882.5330	882.5330
Product Code	GXN	GXN
Indications for Use Statement	The 3D MAC Titanium Cranial Plate (TCP) System is a patient-specific device that is indicated for use to replace bony voids in the cranial and/or craniofacial skeleton (e.g., frontal bone, temporal bone, occipital bone, nasal bone, parietal bone, supraorbital process, lacrimal bone, zygomatic bone, sphenoid bone, ethmoid process, vomer).	The BioArchitects Patient Specific Cranial/Craniofacial Plate implant device is intended to replace bony voids in the cranial and/or craniofacial skeleton (e.g., frontal bone, temporal bone, occipital bone, nasal bone, parietal bone, supraorbital process, lacrimal bone, zygomatic bone, sphenoid bone, ethmoid process, vomer). It is a patient specific device.
Material	Ti6Al4V per ASTM F2924	Ti6Al4V ELI per ASTM F3001-14
Manufacturing Technology	Additive manufacturing: Electron Beam Melting and Vat Photopolymerization	Additive manufacturing: Electron Beam Melting
Anatomical Model Included?	Yes	Not Specified
Fixation to Skull	Commercially available screw systems	Commercially available screw systems
Sterilization	Provided non-sterile, user sterilized	Provided non-sterile, user sterilized

Predicate K151692 Device Comparison

The intended use of the subject device 3D MAC TCP System and predicate K151692 device are the same (replacing voids in the cranial and craniofacial skeleton). The subject device and predicate K151692 device have the following same technological characteristics:

- Method of manufacturing (Implant): Additive manufacturing using powder bed fusion technology
- Method of design: Patient-specific design that is approved by the surgeon before implantation
- Method of fixation: Commercially available screws
- Sterilization: Provided non-sterile, will be steam sterilized by end user

The subject and predicate devices have the following different technological characteristics:

- Material: Ti6Al4V per ASTM F2924 (Subject) and Ti6Al4V ELI per ASTM F3001-14 (Predicate)

This difference in technological characteristics does not raise different questions of safety and effectiveness because the material alloy differences can be evaluated using biocompatibility and performance testing.

Summary of Performance Testing

Multiple nonclinical tests were performed to determine the substantial equivalence of the subject device 3D MAC TCP System. The following tests are listed below:

- Biocompatibility testing
- Static mechanical testing
- Dynamic mechanical testing
- Design validation testing
- Magnetic Resonance (MR) compatibility testing (for labeling)

Biocompatibility Testing

The 3D MAC TCP System comes in contact with tissue/bone and is implanted. The 3D MAC TCP System was evaluated for biocompatibility endpoints and the following tests and results are shown in the following table:

Test	Conclusion
Cytotoxicity (ISO 10993-5)	Non-cytotoxic
Sensitization (ISO 10993-10)	Non-sensitizing
Irritation (ISO 10993-23)	Non-irritating
Acute Systemic Toxicity (ISO 10993-11)	Non-toxic
Material-Mediated Pyrogenicity (ISO 10993-11)	Non-pyrogenic
Implantation Effects (ISO 10993-6)	No unexpected results
Chemical Characterization (ISO 10993-18)	Acceptable margin of safety for all reported extractable substances
Hemolysis (ASTM F756)	Non-hemolytic

Static and Dynamic Mechanical Testing

Static and dynamic mechanical tests were performed to support the substantial equivalence of the 3D MAC TCP System. A static compression test was performed and the 3D MAC TCP System was shown to be able to withstand loads expected in a clinical setting. A dynamic impact test was performed and all 3D MAC TCP System samples passed the acceptance criteria.

Design Validation Testing

A design validation was performed to validate the design and manufacturing of the TCP System by trained neurosurgeons in a mock implantation. Three different engineer designers, three different cases of differing complexities, and three different neurosurgeons were involved in the design validation testing. The neurosurgeons were able to successfully complete the mock implantation design validation, and they found the TCP System acceptable and meets their predefined user needs.

MR Compatibility Testing (for MR Conditional Labeling)

MR compatibility testing was performed to determine the conditions under which a patient implanted with the TCP System could safely undergo an MRI scan. The MR Conditional language is included in the labeling. This testing was performed based on FDA's guidance document, "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment."

Conclusion

Based on the comparison of the intended use and results of the performance testing, the 3D MAC TCP System is substantially equivalent to the predicate device.