April 9, 2026

CG Bio Co., Ltd.
Youngwook Moon
Official Correspondent
3rd Floor, Hannam Bd. 211, Itaewon-Ro, Yongsan-gu
Seoul, 04349
Republic Of Korea

Re: K252251
Trade/Device Name: EASYMADE TI
Regulation Number: 21 CFR 882.5330
Regulation Name: Preformed Nonalterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: GXN
Dated: July 18, 2025
Received: July 18, 2025

Dear Youngwook Moon:

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: 2026.04.09 17:14:00 -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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252251

Please provide the device trade name(s).

EASYMADE TI

Please provide your Indications for Use below.

EASYMADE TI is a patient-specific titanium implant that is designed individually for each patient. The device is intended for use in selective trauma of the cranial skeleton and non-load-bearing craniofacial regions (e.g., frontal bone, temporal bone, occipital bone, parietal bone, sphenoid bone, supraorbital process, vomer), cranial surgery, and reconstructive procedures.

Please select the types of uses (select one or both, as applicable).

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

510(k) Summary

1.	**Company/Applicant**	CG Bio Co, Ltd. 1, Sangwon 12-gil, Seongdong-gu, Seoul, Republic of Korea, 04791 +82-2-550-8300
2.	**Company Contact**	cgra@cgbio.co.kr
3.	**Official Correspondent**	Youngwook Moon (moon@cgbio.co.kr)
4.	**Proprietary Trade Name**	EASYMADE TI
5.	**Common Name**	Patient-Specific Titanium Mesh Implant
6.	**Classification Name**	Plate, Cranioplasty, Preformed, Non-Alterable
	Regulation Number	882.5330
	Classification	Class II
	Product Codes	GXN
7.	**Date Prepared**	04/09/2026

General Description

The subject device, EASYMADE TI, is a patient-specific titanium implant designed for the reconstruction of cranial and non-load-bearing craniofacial defects. The implant is created from patient CT scan data and manufactured using a Laser Powder Bed Fusion (LPBF) additive manufacturing process.

The device is fabricated from Ti-6Al-4V ELI (Grade 23) titanium alloy in full compliance with ASTM F136 and ASTM F3001. The product is supplied non-sterile and must be sterilized by the end user using the validated steam sterilization cycles described in the IFU.

Depending on anatomical location and clinical requirements, the implant may be produced in either a mesh-type or solid-type configuration.

The device is intended to be fixed using FDA-cleared titanium cranial fixation screws; a representative validated fixation system used in performance testing was the JEIL Medical LeForte Neuro System Bone Screw (510(k)

K141452), which is a separate cleared component and not part of the subject device.

Indications for Use

EASYMADE TI is a patient-specific titanium implant that is designed individually for each patient. The device is intended for use in selective trauma of the cranial skeleton and non-load-bearing craniofacial regions (e.g., frontal bone, temporal bone, occipital bone, parietal bone, sphenoid bone, supraorbital process, vomer), cranial surgery, and reconstructive procedures.

Predicate Devices

The subject device is substantially equivalent to the following predicate devices:

Primary Predicate:

K210099: Meticuly Patient-Specific Titanium Mesh Implant, Meticuly Co., Ltd.

Additional Predicate Devices:

K151692: BioArchitects Patient Specific Cranial/Craniofacial Plate, BioArchitects USA, LLC

K220357: MedCAD AccuShape Titanium Patient-Specific Cranial Implant, MedCAD

Summary of the Technological Characteristics with the Predicate Devices

The EASYMADE TI patient-specific titanium implant is substantially equivalent to other legally marketed predicate devices cleared by the U.S. FDA, including Meticuly (K210099), BioArchitects (K151692), and MedCAD (K220357). The primary predicate device is Meticuly Patient-Specific Titanium Mesh Implant (K210099). The subject device shares the same product code (GXN), classification (Class II), intended use, and core technological features as the predicate devices.

Comparison of Technological Characteristics with the Predicate Devices

Feature	EASYMADE TI (Subject Device)	Meticuly (K210099)	BioArchitects (K151692)	MedCAD (K220357)
Product Code	GXN	GXN	GXN	GXN
Classification Regulation	21 CFR 882.5330	Same	Same	Same
Device Classification	Class II	Class II	Class II	Class II
Indications for Use	Fixation and reconstruction of cranial and craniofacial bony defects	Cranial and craniofacial defect reconstruction	Replacement of bony voids in cranial/craniofacial skeleton	Cranial defect correction
Anatomical Sites	Cranial, craniofacial, orbital	Cranial/craniofacial, orbital	Cranial/craniofacial, orbital	Cranial only
Patient-Specific Design	Yes	Yes	Yes	Yes
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F3001)	CP Titanium (Grade 2, ASTM F67)
Manufacturing Method	3D Printing (LPBF)	3D Printing (LPBF)	3D Printing (EBM)	CNC Milling
Design Origin	CT scan based	CT scan based	CT or MRI based	CT based
Sterilization	Supplied non-sterile; user steam sterilization required	Same	Same	Same
Structure Type	Mesh or Solid	Mesh only	Mesh or Solid	Solid only
Fixation Method	Commercially available titanium screws	Same	Same	Same
Reusability	Single-use only	Same	Same	Same
Surface Finish	Sandblasted	Sandblasted	Unspecified	CNC machined
Dimensional Range	10–150 mm (L/W), 1.5–35 mm (H), 1.5–3.0 mm (T)	Similar (not specified)	Similar (not specified)	Not specified
Pore Size (Mesh)	750–950 µm	Not disclosed	Not disclosed	N/A

Key technological characteristics include:

- **Design**: Patient-specific implant based on CT imaging data
- **Material Composition**: Ti-6Al-4V ELI (Grade 23), conforming to ASTM F136
- **Manufacturing Method**: Laser Powder Bed Fusion (LPBF) additive manufacturing
- **Intended Use**: Reconstruction of cranial and craniofacial bony defects
- **Structure**: Mesh and solid types available depending on clinical need
- **Fixation Method**: Predefined screw holes for FDA-cleared titanium cranial fixation screws; the representative validated system used in performance testing was JEIL Medical LeForte Neuro System Bone Screw (510(k) K141452).
- **Sterilization**: Supplied non-sterile; user to perform steam sterilization

Non-clinical testing

Non-clinical performance testing was conducted to support the substantial equivalence of EASYMADE TI. Testing included mechanical performance evaluation, biological evaluation, and software verification activities applicable to the device design and manufacturing workflow.

Mechanical performance testing included evaluation of pore size, surface hardness, density, porosity, flange bending performance, and compression strength with fixation assessment using an FDA-cleared cranial fixation screw system. The results demonstrated that the subject device met the applicable performance criteria and supports substantial equivalence to the predicate devices.

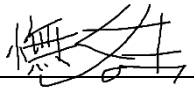
Biocompatibility was evaluated through a risk-based biological evaluation for the final finished device. The evaluation considered the device material, additive manufacturing process, post-processing, cleaning, packaging, and user-performed sterilization, and was supported by verification activities relevant to biological safety.

Software verification testing was performed for the software used in the device design and manufacturing workflow. Verification activities confirmed image/data import consistency, model conversion accuracy, patient-specific design reproducibility, implant thickness consistency, file integrity, mesh repair, support and orientation control, and slicing parameter application for manufacturing preparation.

Conclusion

Based on the comparison with legally marketed predicate devices and the results of non-clinical performance testing, including mechanical performance evaluation, biological evaluation, and software verification activities, the EASYMADE TI patient-specific implant is determined to be substantially equivalent in terms of design, materials, intended use, and overall performance. Differences in manufacturing process, dimensional range, or design structure are supported by validated testing and do not affect the device's safety or effectiveness.

Date: 04/09/2026



Youngwook Moon/ CG Bio Co., Ltd.