July 30, 2026

T&R Biofab Co., Ltd.
℅ Juyeon Ryu
RA Specialist
K-Bio Solutions
Suite 701, Lawyers Tower, 125 Seochojungang-Ro, Seocho-Gu
Seoul, 06644
Republic Of Korea

Re: K251959
Trade/Device Name: TnR Cranial Implant
Regulation Number: 21 CFR 882.5300
Regulation Name: Methyl Methacrylate For Cranioplasty
Regulatory Class: Class II
Product Code: GXP
Dated: July 1, 2026
Received: July 1, 2026

Dear Juyeon Ryu:

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: 2026.07.30 10:10:34 -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)*
K251959

Device Name
TnR Cranial Implant

Indications for Use *(Describe)*
The TnR Cranial Implant is indicated for use in the repair of neurosurgical burr holes, craniotomy cuts, and other cranial defects. It is also for use in the augmentation or restoration of bony contour in the 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.

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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The assigned 510(k) Number: K251959

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Submitter's Information

- Sponsor Name: T&R Biofab Co., Ltd.
- Submitter Name: Kyungho Ji
- Address: 96, Mayu-ro, Siheung-si, Gyeonggi-do, Republic of Korea
- Postal Code: 15111
- Tel: +82-31-431-3344/ Fax: +82-31-431-3302
- E-mail: khji@tnrbiofab.com

2. Date of the summary prepared: July 29, 2026

3. Subject Device Information

- Type of 510(k): Traditional
- Trade Name: TnR Cranial Implant
- Classification Name: Methyl methacrylate for cranioplasty
- 510(k) Number: K251959
- Review Panel: Neurology
- Product Code: GXP
- Regulation: 21 CFR 882.5300
- Regulatory Class: Class II

4. Predicate Device Information

- Sponsor: Osteopore Inc.
- Trade Name: Osteopore PCL Scaffold Bone Void Filler
- Classification Name: Methyl methacrylate for cranioplasty
- 510(k) Number: K051093
- Product Code: GXP
- Regulation Number: 21 CFR 882.5300
- Regulation Class: Class II

5. Device Description

The TnR Cranial Implant is a 3D printed, synthetic, porous, osteoconductive, bone void filler made from polycaprolactone (PCL) and β-tricalcium phosphate (β-TCP) which degrades and resorbs in vivo. The TnR Cranial Implant has an interconnected porous structure.

1) TnR Cranial Implant A (Model No.: GF)

Model Name	Width (A)	Length (B)	Thickness (C)	Height (D)	Top Width (E)	Middle Width (F)
GF3-1533	15.0	33.2	0.4	4.6	2.7	2.3
GF4-1544	15.0	44.5	0.4	4.6	2.7	2.3
GF5-1555	15.0	55.8	0.4	4.6	2.7	2.3
GF6-1567	15.0	67.1	0.4	4.6	2.7	2.3
GF7-1578	15.0	78.4	0.4	4.6	2.7	2.3
GF8-1589	15.0	88.7	0.4	4.6	2.7	2.3
GF9-151H	15.0	100.0	0.4	4.6	2.7	2.3
GF3-2433	24.0	33.2	0.4	4.6	2.7	2.3
GF4-2444	24.0	44.5	0.4	4.6	2.7	2.3
GF5-2455	24.0	55.8	0.4	4.6	2.7	2.3
GF6-2467	24.0	67.1	0.4	4.6	2.7	2.3
GF7-2478	24.0	78.4	0.4	4.6	2.7	2.3
GF8-2489	24.0	88.7	0.4	4.6	2.7	2.3
GF9-241H	24.0	100.0	0.4	4.6	2.7	2.3

2) TnR Cranial Implant B (Model No.: EV)

Model Name	Inner Diameter (A)	Outer Diameter (B)	Thickness (C)	Height (D)
EV-0721	7.0	21.0	0.6	4.6
EV-0822	8.0	22.0	0.6	4.6
EV-0923	9.0	23.0	0.6	4.6
EV-1024	10.0	24.0	0.6	4.6
EV-1125	11.0	25.0	0.6	4.6
EV-1226	12.0	26.0	0.6	4.6
EV-1327	13.0	27.0	0.6	4.6
EV-1428	14.0	28.0	0.6	4.6
EV-1529	15.0	29.0	0.6	4.6

3) TnR Cranial Implant C (Model No.: GP)

Model Name	Length (A)	Width (B)	Thickness (C)
GP10-3015	30	15	1.0
GP10-4015	40	15	1.0
GP10-5015	50	15	1.0

6. Indications for Use

The TnR Cranial Implant is indicated for use in the repair of neurosurgical burr holes, craniotomy cuts, and other cranial defects. It is also for use in the augmentation or restoration of bony contour in the cranial skeleton.

7. Comparison to Predicate Device

The technological characteristics of the TnR Cranial Implant (K251959) were compared to those of the predicate device, Osteopore PCL Scaffold Bone Void Filler (K051093). Where differences exist, they were evaluated through appropriate non-clinical testing and do not raise different questions of safety and effectiveness.

Comparison Item	**Proposed Device, TnR Cranial Implant, K251959**	**Predicate Device, Osteopore PCL Scaffold Bone Void Filler, K051093**
510(k) Number	K251959	K051093
Trade/Device Name	TnR Cranial Implant	Osteopore PCL Scaffold Bone Void Filler
Manufacturer	T&R Biofab Co., Ltd.	Osteopore International Pte Ltd.
Indications for Use	The TnR Cranial Implant is indicated for use in the repair of neurosurgical burr holes, craniotomy cuts, and other cranial defects. It is also for use in the augmentation or restoration of bony contour in the cranial skeleton.	The Osteopore PCL Scaffold™ Bone Filler is intended for use in the repair of neurosurgical burr holes, craniotomy cuts and other cranial defects. It is also for use in the augmentation or restoration of bony contour in the craniofacial skeleton.
Materials	• PCL (Polycaprolactone) • β-TCP (β-tricalcium phosphate)	• PCL (poly-Ɛ-caprolactone)
Resorption Time	18 - 24 months	Not available
Osteoconductive	Osteoconductive	Osteoconductive
Design	Interconnected macroporous structure	Interconnected macroporous structure
Pore Size (range)	150-1600 μm	Not available
Single Use	Yes	Yes
Sterilization	Electron beam sterilization	Provided sterile
Shelf Life	2-year shelf life	Not available

8. Performance Data

The following performance data were provided in support of the substantial equivalence determination of the TnR Cranial Implant.

Biocompatibility Testing

TnR Cranial Implant falls under the category of implant device in contact with tissue and/or bone with permanent contact duration (>30 days) (FDA 2023). Based on this categorization, TnR Cranial Implant has been evaluated on a risk basis for biocompatibility endpoints according to ISO 10993-1 and FDA's modified biocompatibility matrix Table A.1 as listed in Attachment A of the FDA guidance, *Use of International Standard ISO 10993- 1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*.

Test	Test Method Summary	Results and Relevance to SE
Cytotoxicity	Conducted in accordance with ISO 10993-5 using extracts of the sterilized finished device. The purpose of the test was to evaluate in vitro cytotoxic potential of device extracts on cultured mammalian cells.	No cytotoxic response was observed. The device met the acceptance criteria defined in ISO 10993-5. These results demonstrate that the TnR Cranial Implant does not pose cytotoxic risk and does not raise different questions of safety compared to the predicate device.
Sensitization (GPMT)	Performed in accordance with ISO 10993-10 using the Guinea Pig Maximization Test to assess delayed dermal sensitization potential.	No evidence of sensitization was observed. Acceptance criteria were met. The results support long-term implantation safety and do not raise new safety concerns relative to the predicate device.
Intracutaneous Irritation	Conducted per ISO 10993-10 by intracutaneous injection of device extracts to evaluate local irritation potential.	No irritation exceeding acceptance criteria was observed. Results support comparable local tissue response and substantial equivalence.
Acute Systemic Toxicity	Performed in accordance with ISO 10993-11 to assess systemic toxicity following	No systemic toxicity was observed. The device met ISO acceptance criteria. These findings support

	administration of device extracts.	systemic safety comparable to the predicate device.
Subchronic Toxicity	Conducted per ISO 10993-11 to evaluate potential systemic toxicity following repeated exposure.	No treatment-related adverse effects were observed. The results support safety for permanent implantation and do not raise different questions of safety and effectiveness.
Genotoxicity – Ames Test	Bacterial reverse mutation assay performed in accordance with ISO 10993-3 to assess mutagenic potential.	No mutagenic response was observed in any tested strain. The device met acceptance criteria and does not pose genotoxic risk.
Genotoxicity – Mammalian Cell Gene Mutation (MLA)	Mammalian cell gene mutation assay conducted per ISO 10993-3 to evaluate gene mutation potential.	No evidence of gene mutation was detected. These findings support genetic safety comparable to the predicate device.
Material-Mediated Pyrogenicity	Conducted per USP <151> to evaluate pyrogenic response to device extracts.	No pyrogenic response was observed. The device met USP acceptance criteria. Results support systemic safety.
Implantation	Conducted per ISO 10993-6 and the FDA Guidance "General Considerations for Animal Studies Intended to Evaluate Medical Devices" to assess local effects. Please refer to Section 9 for detailed information.	Please refer to Section 9 for summary results.
Endotoxin	Conducted per USP <85> and FDA requirements using the Kinetic-Chromogenic test method to evaluate endotoxin concentration in the test extract.	No endotoxin levels exceeding the USP requirements were detected. The concentration of endotoxin was < 0.00500 EU/mL and < 0.200 EU/device, which meets the current USP acceptance criteria (< 2.15 EU/device).

Hemolysis	Conducted based on ASTM F756, Standard Practice for Assessment of Hemolytic Properties of Materials and ISO10993-4 to evaluate potential to cause hemolysis.	No hemolytic activity was observed. The hemolytic index for direct contact was -0.1%, and the hemolytic index for the extract was 0.3%. Both the test article in direct contact with blood and the test article extract were non-hemolytic.
Chemical Characterization (Extractables)	Performed in accordance with ISO 10993-18 to identify and characterize potential extractable substances. Toxicological risk assessment was conducted based on identified compounds.	No extractables of toxicological concern were identified. Toxicological risk assessment concluded acceptable margins of safety. These data support chemical safety and substantial equivalence.

Bench Testing

Bench testing was conducted to confirm that the TnR Cranial Implant meets predefined design and performance specifications and is substantially equivalent to the predicate device. Visual inspection, dimensional verification, and microstructural evaluation confirmed conformance to design specifications and demonstrated the intended interconnected macroporous architecture. Mechanical tensile strength testing under simulated clinical loading conditions showed that all samples met established acceptance criteria, supporting adequate structural integrity and comparable performance to the predicate. In vitro degradation testing demonstrated a resorption profile consistent with the claimed timeframe and comparable to the predicate device, without raising new performance concerns.

Bench Testing: The following bench testing was conducted on the TnR Cranial Implant

Test	Test Method Summary	Results and Relevance to SE
Appearance, Dimension, Microstructure	Visual inspection and dimensional verification performed to confirm conformance to design specifications. Microstructure evaluated to confirm interconnected macroporous architecture.	All samples met predefined design specifications. Results confirm consistency with intended design and comparable structural characteristics to the predicate device.

Tensile Strength Test	Mechanical testing performed under simulated clinical loading conditions to evaluate structural integrity.	All samples met predefined mechanical acceptance criteria. Results demonstrate adequate structural integrity and performance comparable to the predicate device.
Degradation Test	In vitro degradation testing performed to evaluate resorption profile over time under controlled conditions.	Degradation profile supported the claimed resorption timeframe and was comparable to the predicate device. Results do not raise new performance concerns.
Suture Test	Mechanical testing was performed under simulated clinical loading conditions using a Universal Testing Machine to evaluate suture strength, with a minimum threshold of 3.807 MPa established based on the predicate device	All samples met predefined mechanical acceptance criteria. Results demonstrate adequate structural integrity and performance comparable to the predicate device.

9. Animal Study

An *in vivo* GLP-compliant animal study was conducted in accordance with ISO 10993-6 and 21 CFR Part 58 to evaluate local tissue response and bone regeneration of the TnR Cranial Implant. The study utilized a rabbit cranial defect model (New Zealand White rabbits). Two approximately 6 mm circular craniotomy defects with associated dural defects were created unilaterally in 69 rabbits.

Animals were assigned to three groups (n=23 per group): TnR Cranial Implant, predicate comparator (OsteoMesh®), and negative control. Animals were evaluated at 1, 4, 13, and 26 weeks post-implantation. Endpoints included gross examination, neurological assessment, body weight monitoring, and histological evaluation of bone, dural tissue, brain tissue, and cervical lymph nodes.

The study demonstrated acceptable local tissue response, no device-related adverse inflammatory reactions, and progressive bone formation comparable to the predicate device. These findings support the safety and performance of the TnR Cranial Implant and do not raise different questions of safety and effectiveness.

10. Conclusion

Based on the results of the biocompatibility testing, bench performance testing, and animal study, the TnR Cranial Implant meets applicable safety and performance requirements. Any differences in technological characteristics between the subject device and the predicate device were evaluated through appropriate non-clinical testing and do not raise new questions of safety and effectiveness. Therefore, the TnR Cranial Implant(K251959) is substantially equivalent to the legally marketed predicate device, Osteopore PCL Scaffold Bone Void Filler (K051093).