FDA 510(k) Premarket Notification

CLEARED

K252958 METICULY Patient-specific titanium mesh implant

Jan 14, 2026
120 days to decision

K252958 · Product code: **GXN** · Neurology
Source: https://www.510kdatabase.net/k252958/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Cranioplasty, Preformed, Non-alterable (GXN)
Date received	Sep 16, 2025
Decision date	Jan 14, 2026
Days to decision	120 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Meticuly Co., Ltd.**
Location	Muang Nonthaburi, TH
Contact	Lohwongwatana Peeranoot
510(k) history	3 submissions · 3 cleared · 2021-2026

REGULATORY CONSULTANT

Consulting firm	**Mdr Solutions Co., Ltd.**
Contact	Paweena U-Thainual

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k252958/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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