

K210099 Meticuly Patient-Specific Titanium Mesh ImplantDec 21, 2021
341 days to decisionK210099 · Product code: **GXN** · Neurology
Source: <https://www.510kdatabase.net/k210099/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Cranioplasty, Preformed, Non-alterable (GXN)
Date received	Jan 14, 2021
Decision date	Dec 21, 2021
Days to decision	341 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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