

K252251 EASYMADE-TIApr 9, 2026
265 days to decisionK252251 · Product code: **GXN** · Neurology
Source: <https://www.510kdatabase.net/k252251/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Cranioplasty, Preformed, Non-alterable (GXN)
Date received	Jul 18, 2025
Decision date	Apr 9, 2026
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	CG Bio Co., Ltd.
Location	Seoul, KR
Contact	Youngwook Moon
510(k) history	5 submissions · 5 cleared · 2013-2026

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