

K250334 Fusion Craniofacial ImplantJul 25, 2025
170 days to decisionK250334 · Product code: **GWO** · Neurology
Source: <https://www.510kdatabase.net/k250334/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Cranioplasty, Preformed, Alterable (GWO)
Date received	Feb 5, 2025
Decision date	Jul 25, 2025
Days to decision	170 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Fusion Skull Implant

APPLICANT

Company	Kelyniam Global, Inc.
Location	New Britain, CT, US
Contact	Elise Bozzuto
510(k) history	4 submissions · 4 cleared · 2011-2025

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