

K261058 CraniUS Plate

Jul 29, 2026
120 days to decision

K261058 · Product code: **GWO** · Neurology
Source: <https://www.510kdatabase.net/k261058/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Cranioplasty, Preformed, Alterable (GWO)
Date received	Mar 31, 2026
Decision date	Jul 29, 2026
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	CraniUS, LLC
Location	Baltimore, MD, US
Contact	Natalie Wisniewski
510(k) history	1 submissions · 1 cleared · 2026-2026