

K250297 TECHFIT Patient-Specific Cranial SystemOct 27, 2025
269 days to decisionK250297 · Product code: **GWO** · Neurology
Source: <https://www.510kdatabase.net/k250297/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Cranioplasty, Preformed, Alterable (GWO)
Date received	Jan 31, 2025
Decision date	Oct 27, 2025
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Techfit Digital Surgery, Inc.
Location	Daytona Beach, FL, US
Contact	Angela Lema
510(k) history	4 submissions · 4 cleared · 2022-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250297/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026