

**K253116 3D MAC Titanium Cranial Plate (TCP) System**Jun 18, 2026  
267 days to decisionK253116 · Product code: **GXN** · Neurology  
Source: <https://www.510kdatabase.net/k253116/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Cranioplasty, Preformed, Non-alterable (GXN)
Date received	Sep 24, 2025
Decision date	Jun 18, 2026
Days to decision	267 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>The Surgeon General, Department of the Army (TSG-DA)</b>
Location	Fort Detrick, MD, US
Contact	Emily Badraslioglu
510(k) history	2 submissions · 2 cleared · 2024-2026

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