

**K141644 INNOVASIS CRANIAL SYSTEM**Nov 7, 2014  
141 days to decisionK141644 · Product code: **GWO** · Neurology  
Source: <https://www.510kdatabase.net/k141644/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Cranioplasty, Preformed, Alterable (GWO)
Date received	Jun 19, 2014
Decision date	Nov 7, 2014
Days to decision	141 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Innovasis, Inc.</b>
Location	Salt Lake City, UT, US
Contact	MARSHALL MCCARTY
510(k) history	33 submissions · 32 cleared · 2004-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k141644/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 5, 2026