

**K181539 OSSDSIGN Cranioplug**Oct 12, 2018  
123 days to decisionK181539 · Product code: **GXR** · Neurology  
Source: <https://www.510kdatabase.net/k181539/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cover, Burr Hole (GXR)
Date received	Jun 11, 2018
Decision date	Oct 12, 2018
Days to decision	123 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ossdsign AB</b>
Location	Madison, WI, US
Contact	Ulrik Birgersson
510(k) history	6 submissions · 6 cleared · 2014-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181539/> 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 May 26, 2026