

**K161090 Cranial PSI**Jan 19, 2017  
276 days to decisionK161090 · Product code: **GXN** · Neurology  
Source: <https://www.510kdatabase.net/k161090/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Cranioplasty, Preformed, Non-alterable (GXN)
Date received	Apr 18, 2016
Decision date	Jan 19, 2017
Days to decision	276 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/k161090/> 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