

**K190523 Cranial PSI Accessory – Anatomical Model Original,  
Cranial PSI Accessory – Anatomical Model Modified, Cranial  
PSI Accessory – Plastic Drawing Guide, Cranial PSI Accessory  
– Cranial Implant Trial**Oct 10, 2019  
220 days to decisionK190523 · Product code: **PJN** · Neurology  
Source: <https://www.510kdatabase.net/k190523/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Non-alterable Compound For Cranioplasty (PJN)
Date received	Mar 4, 2019
Decision date	Oct 10, 2019
Days to decision	220 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/k190523/> 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