

K212414 OSSDSIGN Cranial PSIOct 1, 2021
59 days to decisionK212414 · Product code: **PJN** · Neurology
Source: <https://www.510kdatabase.net/k212414/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Non-alterable Compound For Cranioplasty (PJN)
Date received	Aug 3, 2021
Decision date	Oct 1, 2021
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	David Weissburg
Contact	David Weissburg

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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