

**K133082 OSTEOSYMBIONICS PATIENT-SPECIFIC CRANIAL PLATE**May 20, 2014  
232 days to decisionK133082 · Product code: **GXN** · Neurology  
Source: <https://www.510kdatabase.net/k133082/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Cranioplasty, Preformed, Non-alterable (GXN)
Date received	Sep 30, 2013
Decision date	May 20, 2014
Days to decision	232 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Osteosymbionics, LLC</b>
Location	Cleveland, OH, US
Contact	NICHOLAS WLKINS
510(k) history	4 submissions · 4 cleared · 2007-2014

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