

K121102 OSTEOSYMBIONICS PEEK CRANIAL IMPLANTAug 8, 2012
119 days to decisionK121102 · Product code: **GXN** · Neurology
Source: <https://www.510kdatabase.net/k121102/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Cranioplasty, Preformed, Non-alterable (GXN)
Date received	Apr 11, 2012
Decision date	Aug 8, 2012
Days to decision	119 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Osteosymbionics, LLC
Location	Cleveland, OH, US
Contact	ELAINE DUNCAN
510(k) history	4 submissions · 4 cleared · 2007-2014

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