

K121818 OSTEOFAB PATIENT SPECIFIC CRANIAL DEVICEFeb 7, 2013
232 days to decisionK121818 · Product code: **GXN** · Neurology
Source: <https://www.510kdatabase.net/k121818/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Cranioplasty, Preformed, Non-alterable (GXN)
Date received	Jun 20, 2012
Decision date	Feb 7, 2013
Days to decision	232 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Oxford Performance Materials
Location	South Windsor, CT, US
Contact	LEIGH AYRES
510(k) history	3 submissions · 3 cleared · 2013-2015

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