

K180064 OsteoFab Patient Specific Cranial DeviceJul 27, 2018
199 days to decisionK180064 · Product code: **GXN** · Neurology
Source: <https://www.510kdatabase.net/k180064/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Cranioplasty, Preformed, Non-alterable (GXN)
Date received	Jan 9, 2018
Decision date	Jul 27, 2018
Days to decision	199 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Oxford Performance Materials, Inc.
Location	South Windsor, CT, US
Contact	M. Beth Pashko
510(k) history	3 submissions · 3 cleared · 2016-2019

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