

K182742 DB-CMFJun 20, 2019
265 days to decisionK182742 · Product code: **GXP** · Neurology
Source: <https://www.510kdatabase.net/k182742/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Methyl Methacrylate For Cranioplasty (GXP)
Date received	Sep 28, 2018
Decision date	Jun 20, 2019
Days to decision	265 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dimensional Bioceramics, LLC
Location	Scotts Valley, CA, US
Contact	Duran N. Yetkinler
510(k) history	5 submissions · 5 cleared · 2017-2021

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