

K161446 Biopor Porous Polyethylene ImplantsSep 27, 2016
125 days to decisionK161446 · Product code: **GWO** · Neurology
Source: <https://www.510kdatabase.net/k161446/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Cranioplasty, Preformed, Alterable (GWO)
Date received	May 25, 2016
Decision date	Sep 27, 2016
Days to decision	125 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ceremed , Inc.
Location	Los Angeles, CA, US
Contact	Chelsea Mitchell
510(k) history	20 submissions · 20 cleared · 2004-2016

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