

**K180513 CustomizedBone Service**May 15, 2018  
77 days to decisionK180513 · Product code: **GXN** · Neurology  
Source: <https://www.510kdatabase.net/k180513/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Cranioplasty, Preformed, Non-alterable (GXN)
Date received	Feb 27, 2018
Decision date	May 15, 2018
Days to decision	77 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Fin-Ceramica Faenza S.P.A.</b>
Location	Faenza, IT
Contact	Marina Monticelli
510(k) history	5 submissions · 5 cleared · 2016-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k180513/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026