

**K171507 CustomizedBone Service**Sep 1, 2017  
101 days to decisionK171507 · Product code: **GXN** · Neurology  
Source: <https://www.510kdatabase.net/k171507/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Cranioplasty, Preformed, Non-alterable (GXN)
Date received	May 23, 2017
Decision date	Sep 1, 2017
Days to decision	101 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/k171507/> 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