

**K240567 CustomizedBone Service**Mar 28, 2024  
28 days to decisionK240567 · Product code: **GXN** · Neurology  
Source: <https://www.510kdatabase.net/k240567/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plate, Cranioplasty, Preformed, Non-alterable (GXN)
Date received	Feb 29, 2024
Decision date	Mar 28, 2024
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Fortrea</b>
Contact	Stephanie Perryman

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k240567/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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