

K193547 CustomizedBone ServiceJan 17, 2020
28 days to decisionK193547 · Product code: **GXN** · Neurology
Source: <https://www.510kdatabase.net/k193547/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plate, Cranioplasty, Preformed, Non-alterable (GXN)
Date received	Dec 20, 2019
Decision date	Jan 17, 2020
Days to decision	28 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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