

K160707 CustomizedBone ServiceDec 17, 2016
278 days to decisionK160707 · Product code: **GXN** · Neurology
Source: <https://www.510kdatabase.net/k160707/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Cranioplasty, Preformed, Non-alterable (GXN)
Date received	Mar 14, 2016
Decision date	Dec 17, 2016
Days to decision	278 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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