

**K192702 DePuy Synthes Craniomaxillofacial Neuro Devices -
MR Conditional**Sep 18, 2020
357 days to decisionK192702 · Product code: **GXN** · Neurology
Source: <https://www.510kdatabase.net/k192702/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Cranioplasty, Preformed, Non-alterable (GXN)
Date received	Sep 27, 2019
Decision date	Sep 18, 2020
Days to decision	357 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Synthes USA Products, LLC
Location	West Chester, PA, US
Contact	Jeffrey Krawiec
510(k) history	60 submissions · 60 cleared · 2010-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192702/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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