

**K033868 SYNTHES (USA) PATIENT SPECIFIC
CRANIAL/CRANIOFACIAL IMPLANTS**Jun 21, 2004
192 days to decisionK033868 · Product code: **GXN** · Neurology
Source: <https://www.510kdatabase.net/k033868/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Cranioplasty, Preformed, Non-alterable (GXN)
Date received	Dec 12, 2003
Decision date	Jun 21, 2004
Days to decision	192 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Synthes (Usa)
Location	Mchenry, IL, US
Contact	LISA M BOYLE
510(k) history	411 submissions · 394 cleared · 1977-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k033868/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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