

**K053199 SYNTHES PATIENT SPECIFIC
CRANIAL/CRANIOFACIAL IMPLANT**

Dec 14, 2005
28 days to decision

K053199 · Product code: **GXN** · Neurology
Source: <https://www.510kdatabase.net/k053199/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plate, Cranioplasty, Preformed, Non-alterable (GXN)
Date received	Nov 16, 2005
Decision date	Dec 14, 2005
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k053199/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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