

K243715 Synthes Patient Specific ImplantsNov 12, 2025
345 days to decisionK243715 · Product code: **GXN** · Neurology
Source: <https://www.510kdatabase.net/k243715/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Cranioplasty, Preformed, Non-alterable (GXN)
Date received	Dec 2, 2024
Decision date	Nov 12, 2025
Days to decision	345 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Synthes GmbH
Location	Zuchwil, CH
Contact	Thomas Shea
510(k) history	7 submissions · 7 cleared · 2024-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243715/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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