

K042986 MODIFICATION TO SYNTHES (USA) (SYNTHES) LOW PROFILE NEURO SYSTEM

Nov 17, 2004
 19 days to decision

K042986 · Product code: **GXR** · Orthopedic
 Source: <https://www.510kdatabase.net/k042986/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Cover, Burr Hole (GXR)
Date received	Oct 29, 2004
Decision date	Nov 17, 2004
Days to decision	19 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.net

Device record: <https://www.510kdatabase.net/k042986/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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