

K131792 SYNTHECCEL DURA REPAIR, SYNTHECCEL DURA ONLAY

Dec 16, 2013
181 days to decision

K131792 · Product code: **GXQ** · Neurology
Source: <https://www.510kdatabase.net/k131792/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dura Substitute (GXQ)
Date received	Jun 18, 2013
Decision date	Dec 16, 2013
Days to decision	181 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Synthes, Inc.
Location	19380, PA, US
Contact	HEATHER GUERIN
510(k) history	8 submissions · 8 cleared · 2011-2013

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k131792/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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