FDA 510(k) Premarket Notification

K131792 SYNTHECEL DURA REPAIR, SYNTHECEL DURA ONLAY

CLEARED

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