

K113071 SYNTHECEL DURA REPLACEMENT DEVICESJan 9, 2012
84 days to decisionK113071 · Product code: **GXQ** · Neurology
Source: <https://www.510kdatabase.net/k113071/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dura Substitute (GXQ)
Date received	Oct 17, 2011
Decision date	Jan 9, 2012
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Synthes
Location	Paoli, PA, US
Contact	ANDREA M TASKER
510(k) history	11 submissions · 11 cleared · 1998-2013

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