

K031850 DURASIS DURAL SUBSTITUTESep 8, 2003
84 days to decisionK031850 · Product code: **GXQ** · Neurology
Source: <https://www.510kdatabase.net/k031850/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dura Substitute (GXQ)
Date received	Jun 16, 2003
Decision date	Sep 8, 2003
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cook Biotech, Inc.
Location	West Lafayette, IN, US
Contact	MARK BLEYER
510(k) history	31 submissions · 31 cleared · 1998-2014

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