

K161370 Durepair Dura Regeneration MatrixNov 2, 2016
169 days to decisionK161370 · Product code: **GXQ** · Neurology
Source: <https://www.510kdatabase.net/k161370/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dura Substitute (GXQ)
Date received	May 17, 2016
Decision date	Nov 2, 2016
Days to decision	169 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic Neurosurgery
Location	Goleta, CA, US
Contact	Manas Lele
510(k) history	28 submissions · 27 cleared · 2001-2025

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