

K161278 Cerafix Dura SubstituteAug 8, 2016
94 days to decisionK161278 · Product code: **GXQ** · Neurology
Source: <https://www.510kdatabase.net/k161278/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dura Substitute (GXQ)
Date received	May 6, 2016
Decision date	Aug 8, 2016
Days to decision	94 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Acera Surgical, Inc.
Location	St. Louis, MO, US
Contact	Matthew MacEwan
510(k) history	7 submissions · 7 cleared · 2016-2025

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