

K043427 DURAGEN II DURAL REGENERATION MATRIXJan 12, 2005
30 days to decisionK043427 · Product code: **GXQ** · Neurology
Source: <https://www.510kdatabase.net/k043427/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dura Substitute (GXQ)
Date received	Dec 13, 2004
Decision date	Jan 12, 2005
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Integra Lifesciences Corp.
Location	Somerville, NJ, US
Contact	DIANA M BORDON
Website	http://www.integra-ls.com/
510(k) history	29 submissions · 29 cleared · 1999-2019

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Device record: <https://www.510kdatabase.net/k043427/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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