

K163456 DuraGen Secure Dural Regeneration MatrixJan 6, 2017
28 days to decisionK163456 · Product code: **GXQ** · Neurology
Source: <https://www.510kdatabase.net/k163456/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dura Substitute (GXQ)
Date received	Dec 9, 2016
Decision date	Jan 6, 2017
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Integra LifeSciences Corporation
Location	Planisboro, NJ, US
Contact	YARA HAMID
510(k) history	65 submissions · 65 cleared · 2004-2025

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