

K251191 Collagen Dura Regeneration Membrane - RepairNov 18, 2025
215 days to decisionK251191 · Product code: **GXQ** · Neurology
Source: <https://www.510kdatabase.net/k251191/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dura Substitute (GXQ)
Date received	Apr 17, 2025
Decision date	Nov 18, 2025
Days to decision	215 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Collagen Matrix, Inc.
Location	Franklin Lakes, NJ, US
Contact	Victoria Augustine
510(k) history	47 submissions · 47 cleared · 2001-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251191/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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