

**K183513 XenoSure Dura Biologic Patch**Jun 13, 2019  
177 days to decisionK183513 · Product code: **GXQ** · Neurology  
Source: <https://www.510kdatabase.net/k183513/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dura Substitute (GXQ)
Date received	Dec 18, 2018
Decision date	Jun 13, 2019
Days to decision	177 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>LeMaitre Vascular, Inc.</b>
Location	Burlington, MA, US
Contact	Xiang Zhang
510(k) history	32 submissions · 32 cleared · 2003-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k183513/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 15, 2026