

**K190882 XenoSure Biologic Patch**Feb 13, 2020  
315 days to decisionK190882 · Product code: **PSQ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k190882/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intracardiac Patch Or Pledget, Biologically Derived (PSQ)
Date received	Apr 4, 2019
Decision date	Feb 13, 2020
Days to decision	315 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Lemaitre Vascular</b>
Location	Burlington, MA, US
Contact	John N. Bradsher
510(k) history	3 submissions · 3 cleared · 2018-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190882/> 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 June 19, 2026