

**K152833 Pruitt F3-S Polyurethane Carotid Shunt**Jan 21, 2016  
114 days to decisionK152833 · Product code: **MJN** · Cardiovascular  
Source: <https://www.510kdatabase.net/k152833/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular Occluding, Temporary (MJN)
Date received	Sep 29, 2015
Decision date	Jan 21, 2016
Days to decision	114 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>LeMaitre Vascular, Inc.</b>
Location	Burlington, MA, US
Contact	ANNA KASSERIS
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/k152833/> 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