

K182916 Pruitt F3 Carotid Shunt, 10 Fr, Pruitt F3 Carotid Shunt, 9 Fr, Pruitt F3 Carotid Shunt, 8 FrNov 16, 2018
29 days to decisionK182916 · Product code: **MJN** · Cardiovascular
Source: <https://www.510kdatabase.net/k182916/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Intravascular Occluding, Temporary (MJN)
Date received	Oct 18, 2018
Decision date	Nov 16, 2018
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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