

**K043023 PRUITT-INAHARA OUTLYING CAROTID SHUNT,
MODELS, 2012-49, 2013-49, 2014-49,2015-49,2016-49, 2017-49**Dec 3, 2004
30 days to decisionK043023 · Product code: **MJN** · Cardiovascular
Source: <https://www.510kdatabase.net/k043023/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Intravascular Occluding, Temporary (MJN)
Date received	Nov 3, 2004
Decision date	Dec 3, 2004
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	LeMaitre Vascular, Inc.
Location	Burlington, MA, US
Contact	SABA MODJARRAD
510(k) history	32 submissions · 32 cleared · 2003-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k043023/> Data sourced from FDA 510(k) public records (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. - Generated May 15, 2026