

K103356 PRUITT CAROTID KITDec 8, 2010
22 days to decisionK103356 · Product code: **MJN** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k103356/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Intravascular Occluding, Temporary (MJN)
Date received	Nov 16, 2010
Decision date	Dec 8, 2010
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k103356/> 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