

K132022 LEMAITRE 8F OCCLUSION CATHETERNov 6, 2013
128 days to decisionK132022 · Product code: **MJN** · Cardiovascular
Source: <https://www.510kdatabase.net/k132022/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular Occluding, Temporary (MJN)
Date received	Jul 1, 2013
Decision date	Nov 6, 2013
Days to decision	128 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k132022/> 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