

**K121839 UNBALLOON NON-OCCLUSIVE MODELING
CATHETER**Aug 8, 2012
47 days to decisionK121839 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k121839/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Jun 22, 2012
Decision date	Aug 8, 2012
Days to decision	47 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/k121839/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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