

K110891 THE UNBALLOON NON-OCCLUSIVE CATHETERSep 13, 2011
167 days to decisionK110891 · Product code: **DQY** · CardiovascularSource: <https://www.510kdatabase.net/k110891/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Mar 30, 2011
Decision date	Sep 13, 2011
Days to decision	167 days
Third-party review	No
Summary / Statement	Summary
Other names	THE UNBALLOON NON-OCCLUSIVE MODELING CATHETER

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/k110891/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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