

K112124 MICROCATHETERAug 19, 2011
25 days to decisionK112124 · Product code: **DQO** · CardiovascularSource: <https://www.510kdatabase.net/k112124/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Jul 25, 2011
Decision date	Aug 19, 2011
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Navilyst Medical, Inc.
Location	Marlborough, MA, US
Contact	WANDA CARPINELLA
Website	http://www.navilystmedical.com/
510(k) history	35 submissions · 33 cleared · 2009-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k112124/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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