

**K113638 NMI 2.8 MICROCATHETER**Jan 5, 2012  
27 days to decisionK113638 · Product code: **DQO** · CardiovascularSource: <https://www.510kdatabase.net/k113638/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Dec 9, 2011
Decision date	Jan 5, 2012
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k113638/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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