

**K123445 NMI COAXIAL MICROINTRODUCER SET**Apr 1, 2013  
144 days to decisionK123445 · Product code: **DRE** · Cardiovascular  
Source: <https://www.510kdatabase.net/k123445/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Nov 8, 2012
Decision date	Apr 1, 2013
Days to decision	144 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/k123445/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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