

**K131260 NMI DIALYSIS CATHETER**Feb 14, 2014  
288 days to decisionK131260 · Product code: **MSD** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k131260/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Catheter, Hemodialysis, Implanted (MSD)
Date received	May 2, 2013
Decision date	Feb 14, 2014
Days to decision	288 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Navilyst Medical, Inc.</b>
Location	Marlborough, MA, US
Contact	Lorraine M Hanley
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/k131260/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 2, 2026