

**K163452 PICC Maximal Barrier Nursing Kit**Feb 3, 2017  
56 days to decisionK163452 · Product code: **LJS** · General Hospital  
Source: <https://www.510kdatabase.net/k163452/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - K
Submission type	Special
Device classification	Catheter, Intravascular, Therapeutic, Long-term Greater Than 30 Days (LJS)
Date received	Dec 9, 2016
Decision date	Feb 3, 2017
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Navilyst Medical, Inc.</b>
Location	Marlborough, MA, US
Contact	Robin Fuller
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/k163452/> 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 1, 2026