

**K150527 Xcela Power Injectable PICC**Mar 31, 2015  
29 days to decisionK150527 · Product code: **LJS** · General Hospital  
Source: <https://www.510kdatabase.net/k150527/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Intravascular, Therapeutic, Long-term Greater Than 30 Days (LJS)
Date received	Mar 2, 2015
Decision date	Mar 31, 2015
Days to decision	29 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/k150527/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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