

K101326 NMI ICSep 2, 2010
114 days to decisionK101326 · Product code: **LJS** · General Hospital
Source: <https://www.510kdatabase.net/k101326/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Catheter, Intravascular, Therapeutic, Long-term Greater Than 30 Days (LJS)
Date received	May 11, 2010
Decision date	Sep 2, 2010
Days to decision	114 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Navilyst Medical, Inc.
Location	Marlborough, MA, US
Contact	NICHOLAS CONDAKES
Website	http://www.navilystmedical.com/
510(k) history	35 submissions · 33 cleared · 2009-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k101326/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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