

K161866 BioFlo Midline CatheterSep 8, 2016
63 days to decisionK161866 · Product code: **FOZ** · General Hospital
Source: <https://www.510kdatabase.net/k161866/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days (FOZ)
Date received	Jul 7, 2016
Decision date	Sep 8, 2016
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161866/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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