FDA 510(k) Premarket Notification

K161866 BioFlo Midline Catheter

CLEARED

Sep 8, 2016
63 days to decision

K161866 · 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