

K091634 NMI FCMar 1, 2010
270 days to decisionK091634 · Product code: **DTL** · CardiovascularSource: <https://www.510kdatabase.net/k091634/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass (DTL)
Date received	Jun 4, 2009
Decision date	Mar 1, 2010
Days to decision	270 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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