

K113198 NMI CONTROL SYRINGE, 7 ML NMI CONTROL SYRINGE, 8 MLNov 28, 2011
28 days to decisionK113198 · Product code: **DXT** · Cardiovascular
Source: <https://www.510kdatabase.net/k113198/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Oct 31, 2011
Decision date	Nov 28, 2011
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k113198/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 2, 2026