

K253526 NAMIC Dilator and Sheath

Jul 29, 2026
258 days to decision

K253526 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k253526/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Nov 13, 2025
Decision date	Jul 29, 2026
Days to decision	258 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medline Industries, LP
Location	Nortfield, IL, US
Contact	Payal Solanki
Website	https://www.medline.com
510(k) history	31 submissions · 31 cleared · 2022-2026

510k Database - www.510kdatabase.net
Device record: <https://www.510kdatabase.net/k253526/> 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 August 12, 2026