

K960310 EPIC INTRODUCER SHEATHFeb 7, 1996
16 days to decisionK960310 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k960310/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Jan 22, 1996
Decision date	Feb 7, 1996
Days to decision	16 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	North American Instrument Corp.
Location	Walker, MI, US
Contact	MARY MEAGHER-RUBIN
510(k) history	28 submissions · 28 cleared · 1983-1996

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k960310/> 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 May 21, 2026