FDA 510(k) Premarket Notification

K960310 EPIC INTRODUCER SHEATH

CLEARED

Feb 7, 1996
16 days to decision

K960310 · Product code: **DYB** · Cardiovascular
Source: 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