

**K022634 CO-AXIAL INTRODUCER NEEDLE**Nov 6, 2002  
90 days to decisionK022634 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k022634/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Aug 8, 2002
Decision date	Nov 6, 2002
Days to decision	90 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Promex, Inc.</b>
Location	Indianapolis, IN, US
Contact	JOSEPH L MARK
510(k) history	18 submissions · 18 cleared · 1994-2002

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k022634/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 20, 2026