

K972684 INNERDYNE RADIALY EXPANDING VASCULAR ACCESS SYSTEMOct 10, 1997
85 days to decisionK972684 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k972684/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Jul 17, 1997
Decision date	Oct 10, 1997
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Innerdyne, Inc.
Location	Salt Lake City, UT, US
Contact	RICK GAYKOWSKI
510(k) history	12 submissions · 12 cleared · 1995-2000

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