

K941428 EXACTA PERCUTANEOUS INTRODUCER SHEATHJul 6, 1994
104 days to decisionK941428 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k941428/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Mar 24, 1994
Decision date	Jul 6, 1994
Days to decision	104 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Ohmeda Medical
Location	Madison, WI, US
Contact	CHERYL L SHEA
510(k) history	120 submissions · 118 cleared · 1984-2013

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