

**K984260 PINNACLE R/O OR REDIFOCUS INTRODUCER R/O
(COMPRISED OF A SHEATH & DILATOR)**Jan 26, 1999
62 days to decisionK984260 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k984260/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Nov 25, 1998
Decision date	Jan 26, 1999
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Terumo Medical Corp.
Location	Elkton, MD, US
Contact	YUK-TING LEWIS
510(k) history	143 submissions · 143 cleared · 1980-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k984260/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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