FDA 510(k) Premarket Notification

K984260 PINNACLE R/O OR REDIFOCUS INTRODUCER R/O (COMPRISED OF A SHEATH & DILATOR)

CLEARED

Jan 26, 1999
62 days to decision

K984260 · 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