FDA 510(k) Premarket Notification

K062446 MODIFICATION TO PINNACLE ROII HIFLOW INTRODUCER SHEATH

CLEARED

Oct 23, 2006
62 days to decision

K062446 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k062446/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Aug 22, 2006
Decision date	Oct 23, 2006
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Terumo Medical Corp.**
Location	Elkton, MD, US
Contact	MARK UNTERREINER
510(k) history	143 submissions · 143 cleared · 1980-2011