FDA 510(k) Premarket Notification

K081046 PINNACLE DESTINATION PERIPHERAL GUIDING SHEATH

CLEARED

May 21, 2008
37 days to decision

K081046 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k081046/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Apr 14, 2008
Decision date	May 21, 2008
Days to decision	37 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