FDA 510(k) Premarket Notification

K102008 GLIDESHEATH

CLEARED

Jul 21, 2010
5 days to decision

K102008 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k102008/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Jul 16, 2010
Decision date	Jul 21, 2010
Days to decision	5 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

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