FDA 510(k) Premarket Notification

K082644 GLIDESHEATH

CLEARED

Sep 18, 2008
7 days to decision

K082644 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k082644/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Sep 11, 2008
Decision date	Sep 18, 2008
Days to decision	7 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

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