FDA 510(k) Premarket Notification

K012812 CAROTID GUIDING SHEATH

CLEARED

Nov 14, 2001
84 days to decision

K012812 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k012812/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Aug 22, 2001
Decision date	Nov 14, 2001
Days to decision	84 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