FDA 510(k) Premarket Notification

K122960 STEERABLE GUIDING SHEATH, MODEL ADELANTE DESTINO

CLEARED

Dec 13, 2012
79 days to decision

K122960 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k122960/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Sep 25, 2012
Decision date	Dec 13, 2012
Days to decision	79 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Oscor, Inc.**
Location	Palm Harbor, FL, US
Contact	MILA DOSKOCIL
510(k) history	49 submissions · 46 cleared · 1979-2021