FDA 510(k) Premarket Notification

K162322 the POWERWAND Safety Introducer with an Extended Dwell Catheter, 3Fr. Model

CLEARED

Nov 17, 2016
90 days to decision

K162322 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k162322/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Aug 19, 2016
Decision date	Nov 17, 2016
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Access Scientific, LLC**
Location	San Diego, CA, US
Contact	WALTER CORDIGLIA
510(k) history	6 submissions · 6 cleared · 2013-2019