

K131300 THE POWERWAND SAFETY INTRODUCER WITH AN EXTENDED DWELL CATHETERJun 7, 2013
31 days to decisionK131300 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k131300/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	May 7, 2013
Decision date	Jun 7, 2013
Days to decision	31 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k131300/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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