

K121748 THE POWERWAND SAFETY INTRODUCER WITH AND EXTENDED DWELLJul 27, 2012
43 days to decisionK121748 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k121748/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Jun 14, 2012
Decision date	Jul 27, 2012
Days to decision	43 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Access Scientific, Inc.
Location	San Diego, CA, US
Contact	ALBERT MISAJON
510(k) history	8 submissions · 8 cleared · 2008-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k121748/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 14, 2026