

**K183066 The POWERWAND Safety Introducer with an Extended Dwell Catheter made of ChronoFlex C® with BioGUARD™ Technology-3 Fr, 4 Fr, and 5 Fr Model**

Jul 25, 2019  
262 days to decision

K183066 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k183066/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Nov 5, 2018
Decision date	Jul 25, 2019
Days to decision	262 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Access Scientific, LLC</b>
Location	San Diego, CA, US
Contact	Martina Nguyen
510(k) history	6 submissions · 6 cleared · 2013-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k183066/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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