

K181563 The ARTERIAL WAND Safety Introducer with Arterial Catheter made of ChronoFlex C with BioGUARD Technology

Sep 26, 2018
104 days to decision

K181563 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k181563/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Jun 14, 2018
Decision date	Sep 26, 2018
Days to decision	104 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k181563/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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