

K121521 AXERA ACCESS SYSTEMJun 21, 2012
29 days to decisionK121521 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k121521/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	May 23, 2012
Decision date	Jun 21, 2012
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Arstasis, Inc.
Location	San Carlos, CA, US
Contact	DEBRA COGAN
510(k) history	14 submissions · 14 cleared · 2010-2015

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