

K123618 AXERA 2 ACCESS SYSTEMMar 24, 2013
121 days to decisionK123618 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k123618/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Nov 23, 2012
Decision date	Mar 24, 2013
Days to decision	121 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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