

K123135 AXERA 2 ACCESS SYSTEM MODEL AXE200Jan 28, 2013
115 days to decisionK123135 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k123135/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Oct 5, 2012
Decision date	Jan 28, 2013
Days to decision	115 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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