

K140871 AXERA 2 ACCESS SYSTEMJun 6, 2014
63 days to decisionK140871 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k140871/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Apr 4, 2014
Decision date	Jun 6, 2014
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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