

**K132263 AXERA 2 ACCESS SYSTEM**Aug 19, 2013  
28 days to decisionK132263 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k132263/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Jul 22, 2013
Decision date	Aug 19, 2013
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k132263/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 4, 2026