

K113110 AXERA ACCESS SYSTEMNov 9, 2011
20 days to decisionK113110 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k113110/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Oct 20, 2011
Decision date	Nov 9, 2011
Days to decision	20 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k113110/> Data sourced from FDA 510(k) public records (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. - Generated June 4, 2026