

**K103421 ARSTASIS DILATOR ADAPTER**May 24, 2011  
183 days to decisionK103421 · Product code: **DRE** · CardiovascularSource: <https://www.510kdatabase.net/k103421/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Nov 22, 2010
Decision date	May 24, 2011
Days to decision	183 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k103421/> 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