

**K050629 ANGIOSCULPT SCORING BALLOON CATHETER**Sep 2, 2005  
175 days to decisionK050629 · Product code: **PNO** · Cardiovascular  
Source: <https://www.510kdatabase.net/k050629/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous, Cutting/scoring (PNO)
Date received	Mar 11, 2005
Decision date	Sep 2, 2005
Days to decision	175 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Angioscore, Inc.</b>
Location	Alameda, CA, US
Contact	GARY GERSHONY
510(k) history	13 submissions · 13 cleared · 2005-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k050629/> 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 5, 2026