

**K121785 SCEPTER C OCCLUSION BALLOON CATHETER**Aug 10, 2012  
53 days to decisionK121785 · Product code: **MJN** · Cardiovascular  
Source: <https://www.510kdatabase.net/k121785/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular Occluding, Temporary (MJN)
Date received	Jun 18, 2012
Decision date	Aug 10, 2012
Days to decision	53 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>MicroVention, Inc.</b>
Location	Aliso Viejo, CA, US
Contact	Naomi Gong
510(k) history	85 submissions · 85 cleared · 2001-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k121785/> 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 14, 2026