

**K100826 PENUMBRA CATHERER 025**Jul 13, 2010  
111 days to decisionK100826 · Product code: **DQY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k100826/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Mar 24, 2010
Decision date	Jul 13, 2010
Days to decision	111 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Penumbra, Inc.</b>
Location	Alameda, CA, US
Contact	SETH A SCHULMAN
Website	<a href="https://www.penumbrainc.com">https://www.penumbrainc.com</a>
510(k) history	86 submissions · 84 cleared · 2005-2026

Penumbra, Inc. is a global healthcare company headquartered in Alameda, California. The company focuses on innovative medical devices for neurology and cardiovascular interventions. Penumbra has maintained a strong FDA 510(k) regulatory record since its first clearance in 2005. The company has received FDA 510(k) clearances from total submissions. Recent clearances span neurology devices including thrombectomy and access catheters, as well as cardiovascular aspiration systems and delivery catheters. The company remains actively cleared, with the latest FDA 510(k) clearanc...

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