

**K142321 Benchmark Intracranial Access System**Jan 26, 2015  
160 days to decisionK142321 · Product code: **DQY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k142321/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Aug 19, 2014
Decision date	Jan 26, 2015
Days to decision	160 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Penumbra, Inc.</b>
Location	Alameda, CA, US
Contact	Michaela Mahl
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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