

**K201271 Benchmark BMX96 Access System**Jun 11, 2020  
30 days to decisionK201271 · Product code: **DQY** · Neurology  
Source: <https://www.510kdatabase.net/k201271/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	May 12, 2020
Decision date	Jun 11, 2020
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Penumbra, Inc.</b>
Location	Alameda, CA, US
Contact	Matthew Benenati
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...