

**K162901 Penumbra 3D Revascularization Device**Apr 20, 2017  
185 days to decisionK162901 · Product code: **NRY** · Neurology  
Source: <https://www.510kdatabase.net/k162901/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Thrombus Retriever (NRY)
Date received	Oct 17, 2016
Decision date	Apr 20, 2017
Days to decision	185 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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