

**K152699 Apollo System**Mar 17, 2016  
178 days to decisionK152699 · Product code: **GWG** · Neurology  
Source: <https://www.510kdatabase.net/k152699/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscope, Neurological (GWG)
Date received	Sep 21, 2015
Decision date	Mar 17, 2016
Days to decision	178 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Penumbra, Inc.</b>
Location	Alameda, CA, US
Contact	MARY ROSE
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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