

# K242075 Indigo® Aspiration System – Lightning Bolt Aspiration Tubing

Sep 25, 2024  
71 days to decisionK242075 · Product code: **QEW** · Cardiovascular  
Source: <https://www.510kdatabase.net/k242075/>

## SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Peripheral Mechanical Thrombectomy With Aspiration (QEW)
Date received	Jul 16, 2024
Decision date	Sep 25, 2024
Days to decision	71 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	Nikita Patel
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...