

**K192833 Indigo Aspiration System**Dec 20, 2019  
79 days to decisionK192833 · Product code: **QEW** · Cardiovascular  
Source: <https://www.510kdatabase.net/k192833/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Peripheral Mechanical Thrombectomy With Aspiration (QEW)
Date received	Oct 2, 2019
Decision date	Dec 20, 2019
Days to decision	79 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

Company	<b>Penumbra, Inc.</b>
Location	Alameda, CA, US
Contact	Teri Nguyen
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...

**CLINICAL EVIDENCE - NCT03218566****Evaluating the Safety and Efficacy of the Indigo® Aspiration System in Acute Pulmonary Embolism**

Status	Completed
Enrollment	119 patients (actual)
Study sites	22 sites
Condition studied	Pulmonary Embolism
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Apr 5, 2019
Sponsor	Penumbra Inc. (Industry)

**Primary outcome**

Right Ventricle/Left Ventricle (RV:LV) Ratio

**Secondary outcome****Device-related Death Rate**Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT03218566](https://clinicaltrials.gov/study/NCT03218566)