

**K180412 Indigo Aspiration System (CAT RX and Separator 4)-
Penumbra Engine Pump and Canister**May 15, 2018
89 days to decisionK180412 · Product code: **QEW** · Cardiovascular
Source: <https://www.510kdatabase.net/k180412/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Peripheral Mechanical Thrombectomy With Aspiration (QEW)
Date received	Feb 15, 2018
Decision date	May 15, 2018
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Penumbra, Inc.
Location	Alameda, CA, US
Contact	Richard Kimura
Website	https://www.penumbrainc.com
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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Device record: <https://www.510kdatabase.net/k180412/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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