

K190464 Penumbra System 3D Revascularization DeviceApr 26, 2019
59 days to decisionK190464 · Product code: **NRY** · Neurology
Source: <https://www.510kdatabase.net/k190464/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Thrombus Retriever (NRY)
Date received	Feb 26, 2019
Decision date	Apr 26, 2019
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Penumbra, Inc.
Location	Alameda, CA, US
Contact	Denise Aycox
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/k190464/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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