FDA 510(k) Premarket Notification

CLEARED

K250690 Penumbra System (Thunderbolt Aspiration Tubing)

Jun 10, 2026
460 days to decision

K250690 · Product code: **NRY** · Neurology
Source: https://www.510kdatabase.net/k250690/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Thrombus Retriever (NRY)
Date received	Mar 7, 2025
Decision date	Jun 10, 2026
Days to decision	460 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Penumbra, Inc.**
Location	Alameda, CA, US
Contact	Sindokht (Sisi) Soltanzadeh
Website	https://www.penumbrainc.com
510(k) history	87 submissions · 85 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...