FDA 510(k) Premarket Notification

CLEARED

K202821 Indigo Aspiration System - Aspiration Catheter 12 and Separator 12

Nov 18, 2020
55 days to decision

K202821 · Product code: **QEW** · Cardiovascular
Source: https://www.510kdatabase.net/k202821/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Peripheral Mechanical Thrombectomy With Aspiration (QEW)
Date received	Sep 24, 2020
Decision date	Nov 18, 2020
Days to decision	55 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Penumbra, Inc.**
Location	Alameda, CA, US
Contact	Michaela Mahl
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...