FDA 510(k) Premarket Notification

CLEARED

K233201 MIDWAY Delivery Catheter (MIDWAY 43 Delivery Catheter

Mar 27, 2024
181 days to decision

K233201 · Product code: **QJP** · Neurology
Source: https://www.510kdatabase.net/k233201/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous, Neurovasculature (QJP)
Date received	Sep 28, 2023
Decision date	Mar 27, 2024
Days to decision	181 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	MIDWAY 62 Delivery Catheter)

APPLICANT

Company	**Penumbra, Inc.**
Location	Alameda, CA, US
Contact	Sheina Rajkumar
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...