FDA 510(k) Premarket Notification

K111380 NEURON MAX SYSTEM

CLEARED

Jul 19, 2011
64 days to decision

K111380 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k111380/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	May 16, 2011
Decision date	Jul 19, 2011
Days to decision	64 days
Third-party review	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...