FDA 510(k) Premarket Notification

K171332 Artemis Neuro Evacuation Device

CLEARED

Aug 14, 2017
98 days to decision

K171332 · Product code: **GWG** · Neurology
Source: https://www.510kdatabase.net/k171332/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscope, Neurological (GWG)
Date received	May 8, 2017
Decision date	Aug 14, 2017
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Penumbra, Inc.**
Location	Alameda, CA, US
Contact	Mary Rose
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...