FDA 510(k) Premarket Notification

CLEARED

K090752 PENUMBRA SYSTEM (PENNUMBRA REPERFUSION CATHETER 054), MODEL PSC054

Sep 21, 2009
185 days to decision

K090752 · Product code: **NRY** · Neurology
Source: https://www.510kdatabase.net/k090752/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Thrombus Retriever (NRY)
Date received	Mar 20, 2009
Decision date	Sep 21, 2009
Days to decision	185 days
Third-party review	No
Summary / Statement	Summary
Other names	(PENUMBRA SEPARATOR 054), MODEL PSS054

APPLICANT

Company	**Penumbra, Inc.**
Location	Alameda, CA, US
Contact	LOUISE MUSANTE
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...