FDA 510(k) Premarket Notification

K173614 Penumbra Coil 400, Ruby Coil System, POD System

CLEARED

Apr 17, 2018
146 days to decision

K173614 · Product code: **HCG** · Neurology
Source: https://www.510kdatabase.net/k173614/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Neurovascular Embolization (HCG)
Date received	Nov 22, 2017
Decision date	Apr 17, 2018
Days to decision	146 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Penumbra, Inc.**
Location	Alameda, CA, US
Contact	Aditi Kolla
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...