

K070970 NEURON SUPPORT CATHETER SYSTEM, MODEL 5F/6FAug 17, 2007
133 days to decisionK070970 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k070970/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Apr 6, 2007
Decision date	Aug 17, 2007
Days to decision	133 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Penumbra, Inc.
Location	Alameda, CA, US
Contact	THERESA BRANDNER-ALLEN
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...

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Device record: <https://www.510kdatabase.net/k070970/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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