

K051758 PENUMBRA ASPIRATION PUMP, MODEL 115VAug 17, 2005
49 days to decisionK051758 · Product code: **BTA** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k051758/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Portable, Aspiration (manual Or Powered) (BTA)
Date received	Jun 29, 2005
Decision date	Aug 17, 2005
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Penumbra, Inc.
Location	Alameda, CA, US
Contact	THERESA B 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...
