

K183296 REAL Immersive SystemMar 18, 2019
111 days to decisionK183296 · Product code: **ISD** · Physical Medicine
Source: <https://www.510kdatabase.net/k183296/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Exerciser, Measuring (ISD)
Date received	Nov 27, 2018
Decision date	Mar 18, 2019
Days to decision	111 days
Third-party review	No
Combination product	No
PCCP authorized	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...

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k183296/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026