

K250636 Sophy Mini Monopressure Valve (SM1)Nov 28, 2025
270 days to decisionK250636 · Product code: **JXG** · Neurology
Source: <https://www.510kdatabase.net/k250636/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shunt, Central Nervous System And Components (JXG)
Date received	Mar 3, 2025
Decision date	Nov 28, 2025
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sophysa
Location	Orsay, FR
Contact	Lucie Dubois
510(k) history	4 submissions · 4 cleared · 2023-2026

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