

**K252241 Pressio 3 Multi-parameter Neuromonitoring System**Apr 10, 2026  
267 days to decisionK252241 · Product code: **GWM** · Neurology  
Source: <https://www.510kdatabase.net/k252241/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Monitoring, Intracranial Pressure (GWM)
Date received	Jul 17, 2025
Decision date	Apr 10, 2026
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sophysa</b>
Location	Orsay, FR
Contact	Julie Lopez
510(k) history	4 submissions · 4 cleared · 2023-2026

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