

**K162108 Pressio 2 ICP Monitoring System**Apr 17, 2017  
262 days to decisionK162108 · Product code: **GWM** · Neurology  
Source: <https://www.510kdatabase.net/k162108/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Monitoring, Intracranial Pressure (GWM)
Date received	Jul 29, 2016
Decision date	Apr 17, 2017
Days to decision	262 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sophysa SA</b>
Location	Wellesley, MA, US
Contact	Jean-Christophe Audras
510(k) history	9 submissions · 9 cleared · 2000-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162108/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 1, 2026