

K130529 RAUMEDIC-PTO-MONITORING-SYSTEMOct 25, 2013
238 days to decisionK130529 · Product code: **GWM** · Neurology
Source: <https://www.510kdatabase.net/k130529/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Monitoring, Intracranial Pressure (GWM)
Date received	Mar 1, 2013
Decision date	Oct 25, 2013
Days to decision	238 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Raumedic AG
Location	Helmbrechts, DE
Contact	REINER THIEM
510(k) history	6 submissions · 6 cleared · 2011-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k130529/> 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 25, 2026