

**K243339 WiTOF**Jun 23, 2025  
241 days to decisionK243339 · Product code: **KOI** · Anesthesiology  
Source: <https://www.510kdatabase.net/k243339/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Peripheral, Electric (KOI)
Date received	Oct 25, 2024
Decision date	Jun 23, 2025
Days to decision	241 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Idmed</b>
Location	Marseille, FR
Contact	Aurelie Gruener
510(k) history	3 submissions · 3 cleared · 2018-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243339/> 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 May 13, 2026