

**K231166 Levina, Levina Incontinence Stimulation Electrodes  
(Sterile), Pelvic Floor Muscle Probe Electrodes**Jan 18, 2024  
268 days to decisionK231166 · Product code: **KPI** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k231166/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	Apr 25, 2023
Decision date	Jan 18, 2024
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Zmi Electronics , Ltd.</b>
Location	Kaohsiung, TW
Contact	Lawrence Liu
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/k231166/> 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