

**K241862 Levina Pelvic Floor Muscle Stimulator (RS-48)**Mar 27, 2025  
273 days to decisionK241862 · Product code: **KPI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k241862/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	Jun 27, 2024
Decision date	Mar 27, 2025
Days to decision	273 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/k241862/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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