

**K212495 Leva Pelvic Health System**Sep 8, 2021  
30 days to decisionK212495 · Product code: **HIR** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k212495/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Perineometer (HIR)
Date received	Aug 9, 2021
Decision date	Sep 8, 2021
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Renovia, Inc.</b>
Location	Boston, MA, US
Contact	Jim O'Connor
510(k) history	4 submissions · 4 cleared · 2018-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Bold Type</b>
Contact	Jacqueline Schmainda

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212495/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 26, 2026