

K192270 LEva Pelvic Digital Health SystemNov 22, 2019
92 days to decisionK192270 · Product code: **HIR** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k192270/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Perineometer (HIR)
Date received	Aug 22, 2019
Decision date	Nov 22, 2019
Days to decision	92 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Renovia, Inc.
Location	Boston, MA, US
Contact	Gina Prochilo-Cawston
510(k) history	4 submissions · 4 cleared · 2018-2022

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