FDA 510(k) Premarket Notification

K212495 Leva Pelvic Health System

CLEARED

Sep 8, 2021
30 days to decision

K212495 · Product code: **HIR** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k212495/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Bold Type**
Contact	Jacqueline Schmainda

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