FDA 510(k) Premarket Notification

K213913 leva Pelvic Health System

CLEARED

Jun 30, 2022
197 days to decision

K213913 · Product code: **HIR** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k213913/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Perineometer (HIR)
Date received	Dec 15, 2021
Decision date	Jun 30, 2022
Days to decision	197 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

CLINICAL EVIDENCE - NCT04027335

Use of the Leva Pelvic Digital Health System in Women With Fecal Incontinence

Status	Unknown - *No results published to ClinicalTrials.gov*
Enrollment	31 patients (actual)
Study sites	1 site
Condition studied	Fecal Incontinence
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Apr 30, 2021
Sponsor	Renovia, Inc. (Industry)

Primary outcome

St. Mark's Incontinence Score

Secondary outcome

Change in Fecal incontinence episodes

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04027335