FDA 510(k) Premarket Notification

CLEARED

K183468 Revive Reusable Bladder Support

Jan 25, 2019
42 days to decision

K183468 · Product code: **HHW** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k183468/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pessary, Vaginal (HHW)
Date received	Dec 14, 2018
Decision date	Jan 25, 2019
Days to decision	42 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Rinovum Subsidiary 2, LLC**
Location	Monroeville, PA, US
Contact	Shaylee Masilunas
510(k) history	1 submissions · 1 cleared · 2019-2019

CLINICAL EVIDENCE - NCT03323723

Disposable Stress Urinary Incontinence Pessary Device Study

Status	Completed
Enrollment	73 patients (actual)
Study sites	3 sites
Condition studied	Stress Urinary Incontinence
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	May 1, 2018
Sponsor	Rinovum Women's Health, Inc. (Industry)

Primary outcome

Percentage Reduction of Mean Pad Weight Gain (g/hr) During Treatment Phase as Compared to Baseline Phase.

Secondary outcome

Change in Mean SUI Episodes During Treatment Phase as Compared to Baseline Phase

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03323723