FDA 510(k) Premarket Notification

K232830 Vibrant System

CLEARED

Dec 8, 2023
86 days to decision

K232830 · Product code: **QTN** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k232830/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orally Ingested Transient Device For Constipation (QTN)
Date received	Sep 13, 2023
Decision date	Dec 8, 2023
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Vibrant, Ltd.**
Location	Yokneam, IL
Contact	Martha Bezalel, Ph.D.
510(k) history	3 submissions · 2 cleared · 2022-2023

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Janice Hogan

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

CLINICAL EVIDENCE - NCT05036369

Vibrant Capsule vs. Placebo for Patient Suffering From Constipation

Status	Completed
Enrollment	100 patients (actual)
Study sites	2 sites
Condition studied	Constipation Chronic Idiopathic
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Double blind
Completion date	Dec 15, 2022
Sponsor	Vibrant Ltd. (Industry)

Primary outcome

CSBM 1 Success Rate

Secondary outcome

Straining Based on the Subject's Assessment Recorded in Daily Diaries

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05036369