FDA 510(k) Premarket Notification

K223031 Vibrant System

CLEARED

Jan 13, 2023
106 days to decision

K223031 · Product code: **QTN** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k223031/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orally Ingested Transient Device For Constipation (QTN)
Date received	Sep 29, 2022
Decision date	Jan 13, 2023
Days to decision	106 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Vibrant, Ltd.**
Location	Yokneam, IL
Contact	Martha Bezalel
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