

K223031 Vibrant SystemJan 13, 2023
106 days to decisionK223031 · 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](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223031/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026