FDA 510(k) Premarket Notification

K220007 Pure-Vu EVS System

CLEARED

Feb 10, 2022
37 days to decision

K220007 · Product code: **FDF** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k220007/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Colonoscope And Accessories, Flexible/rigid (FDF)
Date received	Jan 4, 2022
Decision date	Feb 10, 2022
Days to decision	37 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Motus GI Medical Technologies , Ltd.**
Location	Tirat Carmel, IL
Contact	Mark Pomeranz
510(k) history	7 submissions · 7 cleared · 2016-2023

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k220007/ 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