FDA 510(k) Premarket Notification

K210981 Pure Vu System

CLEARED

Apr 29, 2021
28 days to decision

K210981 · Product code: **FDF** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k210981/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Colonoscope And Accessories, Flexible/rigid (FDF)
Date received	Apr 1, 2021
Decision date	Apr 29, 2021
Days to decision	28 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