

K210981 Pure Vu SystemApr 29, 2021
28 days to decisionK210981 · 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 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210981/> 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