

K243361 NutrifitDec 19, 2024
51 days to decisionK243361 · Product code: **FPD** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k243361/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Tube, Feeding (FPD) |
| Date received | Oct 29, 2024 |
| Decision date | Dec 19, 2024 |
| Days to decision | 51 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Vygon USA |
| Location | Lansdale, PA, US |
| Contact | Chris Steinke |
| 510(k) history | 4 submissions · 4 cleared · 2018-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243361/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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