FDA 510(k) Premarket Notification

**CLEARED**

# K222880 Endolumik Fluorescence Guided Gastric Calibration Tube (FG Bougie)

Mar 3, 2023
162 days to decision

K222880 · Product code: **KNT** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k222880/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Tubes, Gastrointestinal (and Accessories) (KNT) |
| Date received | Sep 22, 2022 |
| Decision date | Mar 3, 2023 |
| Days to decision | 162 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Endolumik, Inc.** |
| Location | Morgantown, WV, US |
| Contact | Mara McFadden |
| 510(k) history | 1 submissions · 1 cleared · 2023-2023 |

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **Nilo Medical Consulting Group** |
| Contact | Michael Nilo |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov