FDA 510(k) Premarket Notification

**CLEARED**

# K191844 Fidmi Low Profile Enteral Feeding Device

Sep 30, 2019
83 days to decision

K191844 · Product code: **KGC** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k191844/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Tube, Gastro-enterostomy (KGC) |
| Date received | Jul 9, 2019 |
| Decision date | Sep 30, 2019 |
| Days to decision | 83 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Fidmi Medical, Ltd.** |
| Location | Caesarea Business Park, Caesarea, IL |
| Contact | Shahar Millis |
| 510(k) history | 1 submissions · 1 cleared · 2019-2019 |

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **Hogan Lovells US LLP** |
| Contact | Janice M. Hogan |

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