

**K191844 Fidmi Low Profile Enteral Feeding Device**Sep 30, 2019  
83 days to decisionK191844 · 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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Hogan Lovells US LLP</b>
Contact	Janice M. Hogan

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191844/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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