

K190310 U Deliver Bolink ENFit Enteral Feeding SetsMay 31, 2019
108 days to decisionK190310 · Product code: **PIF** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k190310/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastrointestinal Tubes With Enteral Specific Connectors (PIF)
Date received	Feb 12, 2019
Decision date	May 31, 2019
Days to decision	108 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	U Deliver Medical, LLC
Location	Woodbury, MN, US
Contact	Brian Johnson
510(k) history	2 submissions · 2 cleared · 2017-2019

REGULATORY CONSULTANT

Consulting firm	Vista Regulatory Solutions, LLC
Contact	Thomas Dold

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

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