

**K163468 Evolution Duodenal Stent System - Uncovered,
Evolution Colonic Stent System - Uncovered**May 4, 2017
143 days to decisionK163468 · Product code: **MUM** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k163468/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stent, Metallic, Expandable, Duodenal (MUM)
Date received	Dec 12, 2016
Decision date	May 4, 2017
Days to decision	143 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cook Ireland, Ltd.
Location	Limerick, IE
Contact	Jacinta Kilmartin
510(k) history	32 submissions · 27 cleared · 2005-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k163468/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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