

K171619 14Fr Colon Decompression Set, Macon Colon Decompression SetAug 1, 2017
60 days to decisionK171619 · Product code: **FEG** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k171619/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube, Double Lumen For Intestinal Decompression And/or Intubation (FEG)
Date received	Jun 2, 2017
Decision date	Aug 1, 2017
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k171619/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026