

K162330 Flex Robotic System and Flex Colorectal DriveMay 4, 2017
258 days to decisionK162330 · Product code: **FDF** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k162330/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colonoscope And Accessories, Flexible/rigid (FDF)
Date received	Aug 19, 2016
Decision date	May 4, 2017
Days to decision	258 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medrobotics Corporation
Location	Raynham, MA, US
Contact	John D. Bonasera
510(k) history	5 submissions · 5 cleared · 2015-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k162330/> 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 31, 2026