FDA 510(k) Premarket Notification

K162330 Flex Robotic System and Flex Colorectal Drive

CLEARED

May 4, 2017
258 days to decision

K162330 · 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