

K153483 Balloon controller PB-30Dec 15, 2015
12 days to decisionK153483 · Product code: **FDF** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k153483/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Colonoscope And Accessories, Flexible/rigid (FDF)
Date received	Dec 3, 2015
Decision date	Dec 15, 2015
Days to decision	12 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fujifilm Medical Systems U.S.A, Inc.
Location	Stamford, CT, US
Contact	Aaron Ge
510(k) history	39 submissions · 39 cleared · 2005-2018

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