

**K090116 FUJINON COLONOSCOPE FOR DOUBLE BALLOON
ENTERSCOPY SYSTEM MODEL, EC-450B15**Apr 22, 2009
91 days to decisionK090116 · Product code: FDF · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k090116/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colonoscope And Accessories, Flexible/rigid (FDF)
Date received	Jan 21, 2009
Decision date	Apr 22, 2009
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fujinon, Inc.
Location	Washington, DC, US
Contact	MASAYUKI OYATSU
510(k) history	30 submissions · 30 cleared · 1990-2012

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