

K111028 EUS BALLOONNov 1, 2011
202 days to decisionK111028 · Product code: **FDF** · Radiology
Source: <https://www.510kdatabase.net/k111028/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colonoscope And Accessories, Flexible/rigid (FDF)
Date received	Apr 13, 2011
Decision date	Nov 1, 2011
Days to decision	202 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	United States Endoscopy Group, Inc.
Location	Mentor, OH, US
Contact	CARROLL L MARTIN
510(k) history	94 submissions · 92 cleared · 1991-2020

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