FDA 510(k) Premarket Notification

K163492 Oracle EUS Balloon

CLEARED

Jan 6, 2017
24 days to decision

K163492 · Product code: **FDF** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k163492/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Colonoscope And Accessories, Flexible/rigid (FDF)
Date received	Dec 13, 2016
Decision date	Jan 6, 2017
Days to decision	24 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement
Other names	Oracle EUS latex balloon - Olympus Radial; Oracle EUS latex balloon - Olympus Linear; Oracle EUS latex balloon - Fujinon Radial; Oracle EUS latex balloon - Fujinon Linear

APPLICANT

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