FDA 510(k) Premarket Notification

CLEARED

K162622 Fujifilm Endoscope Models EC-600HL and EC-600LS

Oct 18, 2016
28 days to decision

K162622 · Product code: **FDF** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k162622/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Colonoscope And Accessories, Flexible/rigid (FDF)
Date received	Sep 20, 2016
Decision date	Oct 18, 2016
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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