

K162622 Fujifilm Endoscope Models EC-600HL and EC-600LSOct 18, 2016
28 days to decisionK162622 · Product code: **FDF** · Gastroenterology & UrologySource: <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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k162622/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 16, 2026