

**K150221 EPX-4440HD and EPX-4400HD with FICE**Oct 1, 2015  
244 days to decisionK150221 · Product code: **FET** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k150221/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Video Imaging System/component, Gastroenterology-urology (FET)
Date received	Jan 30, 2015
Decision date	Oct 1, 2015
Days to decision	244 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fujifilm Medical System U.S.A., Inc.</b>
Location	Stamford, CT, US
Contact	MARY MOORE
510(k) history	71 submissions · 71 cleared · 1988-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k150221/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 16, 2026