

**K183683 FUJIFILM Double Balloon Endoscopes EN-580T, EC-450BI5, EN-450P5/20, and EN-450T5**Feb 27, 2019  
61 days to decisionK183683 · Product code: FDA · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k183683/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Enteroscope And Accessories (FDA)
Date received	Dec 28, 2018
Decision date	Feb 27, 2019
Days to decision	61 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fujifilm Corporation</b>
Location	Ashigara Kami-Gun, JP
Contact	Randy Vader
510(k) history	63 submissions · 63 cleared · 2018-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Fujifilm Medical Systems U.S.A, Inc.</b>
Contact	Jeffrey Wan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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