

K183032 FUJIFILM Double Balloon Endoscope EI580BTJun 24, 2019
235 days to decisionK183032 · Product code: **FDA** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k183032/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enteroscope And Accessories (FDA)
Date received	Nov 1, 2018
Decision date	Jun 24, 2019
Days to decision	235 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Fujifilm Medical Systems U.S.A, Inc.
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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