FDA 510(k) Premarket Notification

CLEARED

K183683 FUJIFILM Double Balloon Endoscopes EN-580T, EC-450BI5, EN-450P5/20, and EN-450T5

Feb 27, 2019
61 days to decision

K183683 · Product code: **FDA** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k183683/

SUBMISSION DETAILS

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

Company	**Fujifilm Corporation**
Location	Ashigara Kami-Gun, JP
Contact	Randy 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