FDA 510(k) Premarket Notification

CLEARED

K250550 FUJIFILM Endoscope Model EG-S100XT and VS-1000 Display Unit

Feb 17, 2026
357 days to decision

K250550 · Product code: **FDS** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k250550/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastroscope And Accessories, Flexible/rigid (FDS)
Date received	Feb 25, 2025
Decision date	Feb 17, 2026
Days to decision	357 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Fujifilm Corporation**
Location	Ashigara Kami-Gun, JP
Contact	Chaitrali Kulkarni
510(k) history	62 submissions · 62 cleared · 2018-2026

REGULATORY CONSULTANT

Consulting firm	**FUJIFILM Healthcare Americas Corporation**
Contact	Chaitrali Kulkarni

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