FDA 510(k) Premarket Notification

CLEARED

K261880 FUJIFILM Processor EP-8000

Jul 2, 2026
27 days to decision

K261880 · Product code: **FET** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k261880/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Endoscopic Video Imaging System/component, Gastroenterology-urology (FET)
Date received	Jun 5, 2026
Decision date	Jul 2, 2026
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Balloon Controller PB-30;Endoscopy Support Program EW10-VM01

APPLICANT

Company	**Fujifilm Corporation**
Location	Ashigara Kami-Gun, JP
Contact	Chaitrali Kulkarni
510(k) history	65 submissions · 65 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