

K192286 FUJIFILM EP-6000 Video ProcessorMay 1, 2020
253 days to decisionK192286 · Product code: **FET** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k192286/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Video Imaging System/component, Gastroenterology-urology (FET)
Date received	Aug 22, 2019
Decision date	May 1, 2020
Days to decision	253 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	Candace Alva

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

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