

K200850 Fujifilm Ultrasonic ProcessorJul 6, 2020
97 days to decisionK200850 · Product code: **FDS** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k200850/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Gastroscope And Accessories, Flexible/rigid (FDS)
Date received	Mar 31, 2020
Decision date	Jul 6, 2020
Days to decision	97 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 System U.S.A., Inc.
Contact	Kamila Sak

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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