

K214089 FUJIFILM Ultrasonic Processor SP-900 and FUJIFILM Ultrasonic Probe PB2020-M2Jun 3, 2022
157 days to decisionK214089 · Product code: **ODG** · Radiology
Source: <https://www.510kdatabase.net/k214089/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Ultrasound System, Gastroenterology-urology (ODG)
Date received	Dec 28, 2021
Decision date	Jun 3, 2022
Days to decision	157 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	62 submissions · 62 cleared · 2018-2026

REGULATORY CONSULTANT

Consulting firm	FUJIFILM Healthcare Americas Corporation
Contact	Kotei Aoki

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

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