

K221264 FROG Forceps Valve (VAL1-F1-100)Jun 1, 2022
30 days to decisionK221264 · Product code: **ODC** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k221264/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Endoscope Channel Accessory (ODC)
Date received	May 2, 2022
Decision date	Jun 1, 2022
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fujifilm Medwork GmbH
Location	Hochstadt, DE
Contact	Randy Vader
510(k) history	2 submissions · 2 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	FUJIFILM Healthcare Americas Corporation
Contact	Dhara Buch

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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