

K220053 Diathermic Slitter (FlushKnife) DK2620JI and DK2623JIFeb 4, 2022
29 days to decisionK220053 · Product code: **KGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k220053/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Forceps, Biopsy, Electric (KGE)
Date received	Jan 6, 2022
Decision date	Feb 4, 2022
Days to decision	29 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	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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