

**K230751 EW10-EC02 Endoscopy Support Program**Dec 15, 2023  
273 days to decisionK230751 · Product code: **QNP** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k230751/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastrointestinal Lesion Software Detection System (QNP)
Date received	Mar 17, 2023
Decision date	Dec 15, 2023
Days to decision	273 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fujifilm Corporation</b>
Location	Ashigara Kami-Gun, JP
Contact	Randy Vader
510(k) history	62 submissions · 62 cleared · 2018-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>FUJIFILM Healthcare Americas Corporation</b>
Contact	Kotei Aoki

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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