FDA 510(k) Premarket Notification

CLEARED

K230751 EW10-EC02 Endoscopy Support Program

Dec 15, 2023
273 days to decision

K230751 · Product code: **QNP** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k230751/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastrointesinal 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

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