

**K251204 FUJIFILM Stiffening Wire Device (SW-2000)**Sep 26, 2025  
161 days to decisionK251204 · Product code: **FDA** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k251204/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enteroscope And Accessories (FDA)
Date received	Apr 18, 2025
Decision date	Sep 26, 2025
Days to decision	161 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fujifilm Healthcare Americas Corporation</b>
Location	Lexington, MA, US
Contact	Kotei Aoki
510(k) history	12 submissions · 12 cleared · 2023-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251204/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 13, 2026