

K253568 Hood DH-084STRFeb 6, 2026
81 days to decisionK253568 · Product code: **FDS** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k253568/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Gastroscope And Accessories, Flexible/rigid (FDS)
Date received	Nov 17, 2025
Decision date	Feb 6, 2026
Days to decision	81 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Hood DH-094STR; Hood DH-104STR; Hood DH-114STR; Hood DH-124STR; Hood DH-134STR

APPLICANT

Company	Fujifilm Corporation
Location	Ashigara Kami-Gun, JP
Contact	Chaitrali Kulkarni
510(k) history	62 submissions · 62 cleared · 2018-2026

REGULATORY CONSULTANT

Consulting firm	FUJIFILM Healthcare Americas Corporation
Contact	Chaitrali Kulkarni

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253568/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026