

K242635 Endoscopic Distal Attachment (AF-D series)May 30, 2025
269 days to decisionK242635 · Product code: **FDS** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k242635/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastroscope And Accessories, Flexible/rigid (FDS)
Date received	Sep 3, 2024
Decision date	May 30, 2025
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Alton (Shanghai) Medical Instruments Co., Ltd.
Location	Shanghai, CN
Contact	Vivian Li
510(k) history	6 submissions · 6 cleared · 2023-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242635/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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