

**K243039 Ureteral Stents (AF-D series)**Jun 18, 2025  
264 days to decisionK243039 · Product code: **FAD** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k243039/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stent, Ureteral (FAD)
Date received	Sep 27, 2024
Decision date	Jun 18, 2025
Days to decision	264 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243039/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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