FDA 510(k) Premarket Notification

K243039 Ureteral Stents (AF-D series)

CLEARED

Jun 18, 2025
264 days to decision

K243039 · Product code: **FAD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k243039/

SUBMISSION DETAILS

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

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