

**K190659 Ureteral Stent Open Tip/Closed Tip/Intraoperative Tip,
Ureteral Stent via Ureterorenoscope Open Tip/Closed Tip,
Pediatric Ureteral Stent Open Tip/Closed Tip, Mono J Urinary
Diversion Ureteral Stent Open Tip/Closed Tip, Multiloop
Ureteral Stent Open Tip/Closed Tip**Dec 2, 2019
263 days to decisionK190659 · Product code: **FAD** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k190659/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Stent, Ureteral (FAD)
Date received	Mar 14, 2019
Decision date	Dec 2, 2019
Days to decision	263 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Allwin Medical Devices, Inc.
Location	Anaheim, CA, US
Contact	Digish Mehta
510(k) history	7 submissions · 6 cleared · 2019-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190659/> 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 26, 2026