

K201436 Vortek Single Loop Ureteral StentFeb 25, 2021
269 days to decisionK201436 · Product code: **FAD** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k201436/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stent, Ureteral (FAD)
Date received	Jun 1, 2020
Decision date	Feb 25, 2021
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Coloplast Corp.
Location	Marietta, GA, US
Contact	Cori Ragan
510(k) history	54 submissions · 47 cleared · 1985-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201436/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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