

K170362 VORTEK HYDRO-COATED DOUBLE LOOP URETERAL STENTSNov 15, 2017
282 days to decisionK170362 · Product code: **FAD** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k170362/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stent, Ureteral (FAD)
Date received	Feb 6, 2017
Decision date	Nov 15, 2017
Days to decision	282 days
Third-party review	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/k170362/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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