

K180469 ImaJin Silicone Hydro-Coated Double Loop Ureteral StentNov 6, 2018
258 days to decisionK180469 · Product code: **FAD** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k180469/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stent, Ureteral (FAD)
Date received	Feb 21, 2018
Decision date	Nov 6, 2018
Days to decision	258 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

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