

K213186 NovoFlow Reinforced Ureteral StentFeb 16, 2022
140 days to decisionK213186 · Product code: **FAD** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k213186/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Stent, Ureteral (FAD)
Date received	Sep 29, 2021
Decision date	Feb 16, 2022
Days to decision	140 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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