

K242173 Retrace Ureteral Access Sheath (ASXL10, ASXL12, ACXL10, ACXL12, AXXL10, AXXL12, ALXL10, ALXL12)Nov 12, 2024
111 days to decisionK242173 · Product code: **FED** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k242173/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Access Overtube, Gastroenterology-urology (FED)
Date received	Jul 24, 2024
Decision date	Nov 12, 2024
Days to decision	111 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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