FDA 510(k) Premarket Notification

# K181811 ReTrace Ureteral Access Sheath

**CLEARED**

Sep 7, 2018
63 days to decision

K181811 · Product code: **FED** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k181811/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Endoscopic Access Overtube, Gastroenterology-urology (FED) |
| Date received | Jul 6, 2018 |
| Decision date | Sep 7, 2018 |
| Days to decision | 63 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Coloplast A/S** |
| Location | Mchenry, IL, US |
| Contact | Cori Ragan |
| Website | http://www.coloplast.com/ |
| 510(k) history | 71 submissions · 68 cleared · 1983-2023 |

Coloplast A/S is a Danish multinational medical device manufacturer based in McHenry, US. The company develops and markets devices for ostomy, urology, continence, and wound care. Coloplast has received FDA 510(k) clearances from total submissions since its first clearance in 1983. The company's regulatory portfolio is dominated by Gastroenterology & Urology devices, including catheter systems, guidewires, and access sheaths. The latest clearance on record dates to 2023, reflecting the company's historical engagement with FDA regulatory pathways. Notable cleared devices i...