FDA 510(k) Premarket Notification

CLEARED

K123675 RE-TRACE URETERAL ACCESS SHEATH, 10/12 FRENCH, LENGTH 35 AND 45 CM, URETERAL ACCESS SHEATH, 12/14 CH-FR, LENGTH 35CM, UR

Mar 1, 2013
91 days to decision

K123675 · Product code: **FED** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k123675/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Access Overtube, Gastroenterology-urology (FED)
Date received	Nov 30, 2012
Decision date	Mar 1, 2013
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Coloplast A/S**
Location	Mchenry, IL, US
Contact	BRIAN SCHMIDT
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...