FDA 510(k) Premarket Notification

K102485 RE-TRACE URETERAL ACCESS SHEATH

CLEARED

Oct 18, 2010
49 days to decision

K102485 · Product code: **FED** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k102485/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Access Overtube, Gastroenterology-urology (FED)
Date received	Aug 30, 2010
Decision date	Oct 18, 2010
Days to decision	49 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...