

K112322 RESTORELLE POLYPROPYLENE Y MESHMay 17, 2012
279 days to decisionK112322 · Product code: **OTO** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k112322/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Synthetic, Urogynecologic, For Apical Vaginal And Uterine Prolapse, Transabdominally Placed (OTO)
Date received	Aug 12, 2011
Decision date	May 17, 2012
Days to decision	279 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Coloplast A/S
Location	Mchenry, IL, US
Contact	TIM CRABTREE
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...