

K221874 Altis Single Incision Sling SystemFeb 15, 2023
232 days to decisionK221874 · Product code: **PAH** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k221874/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical, Synthetic, Urogynecologic, For Stress Urinary Incontinence, Female, Mini-sling (PAH)
Date received	Jun 28, 2022
Decision date	Feb 15, 2023
Days to decision	232 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Coloplast A/S
Location	Mchenry, IL, US
Contact	Gayatri Ghadge
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...

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