

K121562 ALTIS SINGLE INCISION CLING SYSTEMNov 5, 2012
160 days to decisionK121562 · Product code: **PAH** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k121562/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Mesh, Surgical, Synthetic, Urogynecologic, For Stress Urinary Incontinence, Female, Mini-sling (PAH) |
| Date received | May 29, 2012 |
| Decision date | Nov 5, 2012 |
| Days to decision | 160 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Coloplast A/S |
| Location | Mchenry, IL, US |
| Contact | JANELL A COLLEY |
| 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...
