

K103254 PERISTEEN ANAL IRRIGATION SYSTEM, IRRIGATION ACCESSORY UNIT, IRRIGATION RECTAL CATHETER, SYSTEM STRAP, IRRIGATION TUBEJan 31, 2011
89 days to decisionK103254 · Product code: **KNT** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k103254/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Tubes, Gastrointestinal (and Accessories) (KNT) |
| Date received | Nov 3, 2010 |
| Decision date | Jan 31, 2011 |
| Days to decision | 89 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...