

**K112860 PERISTEEN ANAL IRRIGATION SYSTEM, PERISTEEN ANAL IRRIGATION ACCESSORY UNIT, PERISTEEN ANAL IRRIGATION RECTAL CATHETER**Jun 8, 2012  
252 days to decisionK112860 · Product code: **KNT** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k112860/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubes, Gastrointestinal (and Accessories) (KNT)
Date received	Sep 30, 2011
Decision date	Jun 8, 2012
Days to decision	252 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Coloplast A/S</b>
Location	Mchenry, IL, US
Contact	BRIAN SCHMIDT
Website	<a href="http://www.coloplast.com/">http://www.coloplast.com/</a>
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...