

K083770 COLOPLAST PERISTEEN ANAL IRRIGATION (PAI) SYSTEMNov 23, 2009
340 days to decisionK083770 · Product code: **KNT** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k083770/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubes, Gastrointestinal (and Accessories) (KNT)
Date received	Dec 18, 2008
Decision date	Nov 23, 2009
Days to decision	340 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...