

**K840268 IRRIGATION SYSTEM**Apr 5, 1984  
73 days to decisionK840268 · Product code: **EXD** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k840268/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Irrigator, Ostomy (EXD)
Date received	Jan 23, 1984
Decision date	Apr 5, 1984
Days to decision	73 days
Third-party review	No

**APPLICANT**

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Company	<b>Coloplast A/S</b>
Location	Mchenry, IL, US
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...

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