

**K854580 CONVEEN SELF-SEALING URISHEATH MALE  
EXTERNAL CATH**Dec 13, 1985  
28 days to decisionK854580 · Product code: **KNX** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k854580/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Collector, Urine, (and Accessories) For Indwelling Catheter (KNX)
Date received	Nov 15, 1985
Decision date	Dec 13, 1985
Days to decision	28 days
Third-party review	No

**APPLICANT**

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Company	<b>Coloplast A/S</b>
Location	Mchenry, IL, US
Contact	C/O R HAMMER/ASSOCI
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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