

**K924407 CONVEEN(R) SELF-SEALING URISHEATH MALE
EXTER CATH**Sep 23, 1992
29 days to decisionK924407 · Product code: **EXJ** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k924407/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Incontinence, Urosheath Type, Sterile (EXJ)
Date received	Aug 25, 1992
Decision date	Sep 23, 1992
Days to decision	29 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Coloplast A/S
Location	Mchenry, IL, US
Contact	RICHARD A HAMER
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...

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