FDA 510(k) Premarket Notification

CLEARED

K946243 CONVEEN(R) SELF-SEALING URISHEATH MALE EXTERNAL CATHETER

Feb 13, 1995
53 days to decision

K946243 · Product code: **EXJ** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k946243/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Incontinence, Urosheath Type, Sterile (EXJ)
Date received	Dec 22, 1994
Decision date	Feb 13, 1995
Days to decision	53 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Coloplast A/S**
Location	Mchenry, IL, US
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...