FDA 510(k) Premarket Notification

K895548 CONVEEN INTERMITTENT CATHETERS

CLEARED

Feb 9, 1990
149 days to decision

K895548 · Product code: **KOD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k895548/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Urological (KOD)
Date received	Sep 13, 1989
Decision date	Feb 9, 1990
Days to decision	149 days
Third-party review	No

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...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k895548/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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