FDA 510(k) Premarket Notification

K833571 STERILE DRAINAGE SYSTEM

CLEARED

Jan 30, 1984
110 days to decision

K833571 · Product code: **EXB** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k833571/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Collector, Ostomy (EXB)
Date received	Oct 12, 1983
Decision date	Jan 30, 1984
Days to decision	110 days
Third-party review	No

APPLICANT

Company	**Coloplast A/S**
Location	Mchenry, IL, US
Contact	ANTONIO M OJEDA
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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Device record: https://www.510kdatabase.net/k833571/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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