

K840266 K-FLEX OSTOMY POUCH

Jan 23, 1984

K840266 · Gastroenterology & Urology

Source: <https://www.510kdatabase.net/k840266/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - SP
Submission type	Traditional
Date received	Jan 23, 1984
Decision date	Jan 23, 1984
Third-party review	No

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...

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Device record: <https://www.510kdatabase.net/k840266/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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