

K840362 COMFEEL PASTENov 7, 1984
286 days to decisionK840362 · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k840362/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Date received	Jan 26, 1984
Decision date	Nov 7, 1984
Days to decision	286 days
Third-party review	No

APPLICANT

Company	Coloplast A/S
Location	McHenry, IL, US
Contact	& ASSOCIATE
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...