FDA 510(k) Premarket Notification

K834343 COMFEEL POWDER

CLEARED

Nov 8, 1984
332 days to decision

K834343 · Product code: **KOZ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k834343/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Beads, Hydrophilic, For Wound Exudate Absorption (KOZ)
Date received	Dec 12, 1983
Decision date	Nov 8, 1984
Days to decision	332 days
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...