FDA 510(k) Premarket Notification

K894916 COMFEEL TRANSPARENT DRESSING

CLEARED

Sep 26, 1989
55 days to decision

K894916 · Product code: **KGX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k894916/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tape And Bandage, Adhesive (KGX)
Date received	Aug 2, 1989
Decision date	Sep 26, 1989
Days to decision	55 days
Third-party review	No

APPLICANT

Company	**Coloplast A/S**
Location	Mchenry, IL, US
Contact	RICHARD 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...