

K904085 ELLA BREAST FORMOct 31, 1990
56 days to decisionK904085 · Product code: **KCZ** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k904085/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Breast, External, Used With Adhesive (KCZ)
Date received	Sep 5, 1990
Decision date	Oct 31, 1990
Days to decision	56 days
Third-party review	No

APPLICANT

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