

K904316 NOUVELLE (TM) MODEL #901, SIZES 0-12, LEFT & RIGHTOct 11, 1990
20 days to decisionK904316 · Product code: **KCZ** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k904316/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Breast, External, Used With Adhesive (KCZ)
Date received	Sep 21, 1990
Decision date	Oct 11, 1990
Days to decision	20 days
Third-party review	No

APPLICANT

Company	Coloplast Corp.
Location	Marietta, GA, US
Contact	TRACY L SADOWSKI
510(k) history	54 submissions · 47 cleared · 1985-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k904316/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026