

**K921535 SUOENA AFFINITY (TM) MODEL #802**May 11, 1992  
41 days to decisionK921535 · Product code: **KCZ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k921535/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Breast, External, Used With Adhesive (KCZ)
Date received	Mar 31, 1992
Decision date	May 11, 1992
Days to decision	41 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Coloplast Corp.</b>
Location	Marietta, GA, US
Contact	LEE LEWIS
510(k) history	54 submissions · 47 cleared · 1985-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k921535/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 28, 2026