

**K915382 AMOENA AFFINITY MODEL #802**Jan 14, 1992  
46 days to decisionK915382 · Product code: **KCZ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k915382/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Breast, External, Used With Adhesive (KCZ)
Date received	Nov 29, 1991
Decision date	Jan 14, 1992
Days to decision	46 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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