

**K864785 AMOENA BREAST FORMS**Jan 8, 1987  
31 days to decisionK864785 · Product code: **GBI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k864785/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, External Aesthetic Restoration, Used With Adhesive (GBI)
Date received	Dec 8, 1986
Decision date	Jan 8, 1987
Days to decision	31 days
Third-party review	No

**APPLICANT**

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Company	<b>Coloplast Corp.</b>
Location	Marietta, GA, US
Contact	THOMAS B TAYLOR
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/k864785/>; 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