

K853822 AMOENA BREAST FORMSSep 30, 1985
17 days to decisionK853822 · Product code: **GBI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k853822/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, External Aesthetic Restoration, Used With Adhesive (GBI)
Date received	Sep 13, 1985
Decision date	Sep 30, 1985
Days to decision	17 days
Third-party review	No

APPLICANT

Company	Coloplast Corp.
Location	Marietta, GA, US
Contact	THOMAS B TAYLOR
510(k) history	54 submissions · 47 cleared · 1985-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k853822/>, 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