

K813416 EXTERNAL BREAST PROSTHESISJan 18, 1982
42 days to decisionK813416 · Product code: **GBI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k813416/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, External Aesthetic Restoration, Used With Adhesive (GBI)
Date received	Dec 7, 1981
Decision date	Jan 18, 1982
Days to decision	42 days
Third-party review	No

APPLICANT

Company	Surgical Appliance Industries, Inc.
Location	Mchenry, IL, US
510(k) history	9 submissions · 9 cleared · 1981-2012

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Device record: <https://www.510kdatabase.net/k813416/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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