

**K872714 S.T.A.C.E.M. EXTERNAL BREAST PROSTHESIS  
MAMMARY**

Jul 21, 1987  
11 days to decision

K872714 · Product code: **GBI** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k872714/>

**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         | Jul 10, 1987   |
| Decision date         | Jul 21, 1987   |
| Days to decision      | 11 days  |
| Third-party review    | No   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Roseburg SA</b>                      |
| Location       | Washington, DC, US                      |
| Contact        | DARIENNE MOYER                          |
| 510(k) history | 24 submissions · 23 cleared · 1985-1994 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k872714/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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