

K935341 COMFORT PLUS BREAST SHELLSJan 21, 1994
77 days to decisionK935341 · Product code: **HFS** · General Hospital
Source: <https://www.510kdatabase.net/k935341/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shield, Nipple (HFS)
Date received	Nov 5, 1993
Decision date	Jan 21, 1994
Days to decision	77 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Marshall Baby Products
Location	Vernon Hills, IL, US
Contact	JANE A EHRHARD
510(k) history	2 submissions · 2 cleared · 1994-1994

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k935341/> 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 July 6, 2026