

**K923577 BREAST SHELLS**Jan 22, 1993  
186 days to decisionK923577 · Product code: **HFS** · General Hospital  
Source: <https://www.510kdatabase.net/k923577/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shield, Nipple (HFS)
Date received	Jul 20, 1992
Decision date	Jan 22, 1993
Days to decision	186 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Medela, Inc.</b>
Location	Mchenry, IL, US
Contact	STEPHEN D SMITH
510(k) history	19 submissions · 19 cleared · 1980-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k923577/> 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 1, 2026