

**K924297 DEWETTE 2 ISOLETTE INCUBATOR HUMIDIFIER**Mar 18, 1993  
204 days to decisionK924297 · Product code: **FMZ** · General HospitalSource: <https://www.510kdatabase.net/k924297/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Incubator, Neonatal (FMZ)
Date received	Aug 26, 1992
Decision date	Mar 18, 1993
Days to decision	204 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Air-Shields Vickers, Inc.</b>
Location	Hatboro, PA, US
Contact	FRANCIS X CASEY
510(k) history	9 submissions · 9 cleared · 1988-1995

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k924297/> 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 May 26, 2026