

**K781876 ISOLETTE INCUBATOR**Dec 7, 1978  
35 days to decisionK781876 · Product code: **FMZ** · General Hospital  
Source: <https://www.510kdatabase.net/k781876/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Incubator, Neonatal (FMZ)
Date received	Nov 2, 1978
Decision date	Dec 7, 1978
Days to decision	35 days
Third-party review	No

**APPLICANT**

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Company	<b>Air-Shields, Inc.</b>
Location	Mchenry, IL, US
510(k) history	33 submissions · 33 cleared · 1976-1998

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

Device record: <https://www.510kdatabase.net/k781876/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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