

K914864 MODELS C500/C550 ISOLETE(R) INFANT INCUBATORMar 13, 1992
136 days to decisionK914864 · Product code: **FMZ** · General Hospital
Source: <https://www.510kdatabase.net/k914864/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Incubator, Neonatal (FMZ)
Date received	Oct 29, 1991
Decision date	Mar 13, 1992
Days to decision	136 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Air-Shields, Inc.
Location	Mchenry, IL, US
Contact	FRANCIS X CASEY
510(k) history	33 submissions · 33 cleared · 1976-1998

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