

K913291 MODEL C386 ISOLETTE(R) INFANT INCUBATORNov 13, 1991
112 days to decisionK913291 · Product code: **FMZ** · General Hospital
Source: <https://www.510kdatabase.net/k913291/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Incubator, Neonatal (FMZ)
Date received	Jul 24, 1991
Decision date	Nov 13, 1991
Days to decision	112 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k913291/> 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 May 22, 2026