

K941106 MODEL TI500 ISOLETTE INFANT INCUBATORJun 10, 1994
95 days to decisionK941106 · Product code: **FPL** · General HospitalSource: <https://www.510kdatabase.net/k941106/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Incubator, Neonatal Transport (FPL)
Date received	Mar 7, 1994
Decision date	Jun 10, 1994
Days to decision	95 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/k941106/> 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