

K971256 DUO-LITE PHOTOTHERAPY SYSTEMSep 24, 1997
173 days to decisionK971256 · Product code: **LBI** · General Hospital
Source: <https://www.510kdatabase.net/k971256/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Neonatal Phototherapy (LBI)
Date received	Apr 4, 1997
Decision date	Sep 24, 1997
Days to decision	173 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Air-Shields, Inc.
Location	Mchenry, IL, US
Contact	MARCI L GOLDFINGER
510(k) history	33 submissions · 33 cleared · 1976-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k971256/> 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