

**K951259 ICEL ULTRASONIC NEBULIZER MODELS PU 12000
AND PU 12300**Jun 20, 1995
91 days to decisionK951259 · Product code: **CAF** · Anesthesiology
Source: <https://www.510kdatabase.net/k951259/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Mar 21, 1995
Decision date	Jun 20, 1995
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Impulso Trading Co.
Location	Great Neck,, NY, US
Contact	SUSAN D GOLDSTEIN-FALK
510(k) history	1 submissions · 1 cleared · 1995-1995

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k951259/> 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 26, 2026