

K980024 SHINMED MODEL SW-966 ULTRASONIC NEBULIZERSep 3, 1999
606 days to decisionK980024 · Product code: **CAF** · Anesthesiology
Source: <https://www.510kdatabase.net/k980024/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Jan 5, 1998
Decision date	Sep 3, 1999
Days to decision	606 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Shining World Health Care Co., Ltd.
Location	Hsin Chu City, TW
Contact	CAROLANN KOTULA
510(k) history	4 submissions · 4 cleared · 1999-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k980024/> 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 27, 2026