

**K981078 TRANSTRACHEAL AUGMENTED VENTILATION
OXYGEN CONCENTRATOR MODEL NUMBER TTAV 1000**Jul 23, 1998
121 days to decisionK981078 · Product code: **CAW** · Anesthesiology
Source: <https://www.510kdatabase.net/k981078/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Generator, Oxygen, Portable (CAW)
Date received	Mar 24, 1998
Decision date	Jul 23, 1998
Days to decision	121 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Transtracheal Systems
Location	Denver, CO, US
Contact	LEWIS WARD
510(k) history	8 submissions · 7 cleared · 1986-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k981078/> 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 25, 2026