

K922654 VENTILATOR ADULT STAR MODIFICATIONDec 1, 1992
181 days to decisionK922654 · Product code: **CBK** · Anesthesiology
Source: <https://www.510kdatabase.net/k922654/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Facility Use (CBK)
Date received	Jun 3, 1992
Decision date	Dec 1, 1992
Days to decision	181 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Infrasonics Corp.
Location	Walker, MI, US
Contact	JIM HITCHIN
510(k) history	20 submissions · 19 cleared · 1984-1995

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k922654/> 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