

**K043382 TMS FULL ADVANTAGE FULL FACE MASK, MODELS
TMS-2820, TMS-2830, TMS-2840**Jan 19, 2005
41 days to decisionK043382 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k043382/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Dec 9, 2004
Decision date	Jan 19, 2005
Days to decision	41 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Tiara Medical Systems, Inc.
Location	Lakewood, OH, US
Contact	GEOFFREY SLEEPER
510(k) history	7 submissions · 7 cleared · 1997-2005

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k043382/> 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