

K083656 APEX MEDICAL XT AUTO CPAP 9S-005200Apr 22, 2009
133 days to decisionK083656 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k083656/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Dec 10, 2008
Decision date	Apr 22, 2009
Days to decision	133 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Apex Medical Corp.
Location	Shi-Chih, Taipei Hsien, TW
Contact	ALAN CHANG
510(k) history	30 submissions · 30 cleared · 1997-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k083656/> 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 24, 2026