

K002768 ACAPELLADec 5, 2000
90 days to decisionK002768 · Product code: **BWF** · Anesthesiology
Source: <https://www.510kdatabase.net/k002768/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Therapeutic (incentive) (BWF)
Date received	Sep 6, 2000
Decision date	Dec 5, 2000
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dhd Healthcare Corp.
Location	Wampsville, NY, US
Contact	LAWRENCE WEINSTEIN
510(k) history	8 submissions · 8 cleared · 1998-2004

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k002768/> 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