

**K053149 SPIRO-BALL**Dec 13, 2005  
33 days to decisionK053149 · Product code: **BWF** · Anesthesiology  
Source: <https://www.510kdatabase.net/k053149/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Therapeutic (incentive) (BWF)
Date received	Nov 10, 2005
Decision date	Dec 13, 2005
Days to decision	33 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Leventon, S.A.</b>
Location	Barcelona, ES
Contact	ORIOLE VERNIS
510(k) history	5 submissions · 5 cleared · 1985-2005

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k053149/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 25, 2026