

**K013489 KP + LFM**Nov 29, 2001  
38 days to decisionK013489 · Product code: **BZH** · Anesthesiology  
Source: <https://www.510kdatabase.net/k013489/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Meter, Peak Flow, Spirometry (BZH)
Date received	Oct 22, 2001
Decision date	Nov 29, 2001
Days to decision	38 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Pds Healthcare Products, Inc.</b>
Location	Louisville, CO, US
Contact	JIM LEWIS
510(k) history	2 submissions · 2 cleared · 2001-2001

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k013489/> 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