

**K153441 VibraPEP**Mar 25, 2016  
119 days to decisionK153441 · Product code: **BWF** · Anesthesiology  
Source: <https://www.510kdatabase.net/k153441/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Therapeutic (incentive) (BWF)
Date received	Nov 27, 2015
Decision date	Mar 25, 2016
Days to decision	119 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Medica Holdings, LLC</b>
Location	Lake Oswego, OR, US
Contact	George Reed
510(k) history	3 submissions · 3 cleared · 2016-2018

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k153441/> 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 24, 2026