

**K150173 Aerobika OPEP Devive with Manometer**Oct 15, 2015  
262 days to decisionK150173 · Product code: **BWF** · AnesthesiologySource: <https://www.510kdatabase.net/k150173/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Spirometer, Therapeutic (incentive) (BWF)
Date received	Jan 26, 2015
Decision date	Oct 15, 2015
Days to decision	262 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Trudell Medical International</b>
Location	London, CA
Contact	Darryl Fischer
510(k) history	9 submissions · 9 cleared · 2015-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k150173/> 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 27, 2026