

**K161295 MiniBox +**Oct 21, 2016  
165 days to decisionK161295 · Product code: **BZC** · Anesthesiology  
Source: <https://www.510kdatabase.net/k161295/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calculator, Pulmonary Function Data (BZC)
Date received	May 9, 2016
Decision date	Oct 21, 2016
Days to decision	165 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Pulmone Advanced Medical Devices, Ltd.</b>
Location	Gaithersburg, MD, US
Contact	Avi Lazar
510(k) history	3 submissions · 3 cleared · 2014-2016

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161295/> 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