

**K201493 Spirometer**Jun 10, 2021  
371 days to decisionK201493 · Product code: **BZG** · Anesthesiology  
Source: <https://www.510kdatabase.net/k201493/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Diagnostic (BZG)
Date received	Jun 4, 2020
Decision date	Jun 10, 2021
Days to decision	371 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Mehow Innovative, Ltd.</b>
Location	Shenzhen, CN
Contact	Gloria Sun
510(k) history	1 submissions · 1 cleared · 2021-2021

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Guangzhou Osmunda Medical Device Technical Service Co., Ltd.</b>
Contact	Olivia Meng

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201493/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026