

K203196 Peak flow meterMay 26, 2021
210 days to decisionK203196 · Product code: **BZH** · Anesthesiology
Source: <https://www.510kdatabase.net/k203196/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Meter, Peak Flow, Spirometry (BZH)
Date received	Oct 28, 2020
Decision date	May 26, 2021
Days to decision	210 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shanghai Sonmol Medical Equipment Co., Ltd.
Location	Shanghai, CN
Contact	Li Yong Xu
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Shanghai Sungo Management Consulting Company Limited.
Contact	Raymond Luo

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203196/> 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