

K191239 Smart Peak Flow MeterDec 6, 2019
212 days to decisionK191239 · Product code: **BZH** · Anesthesiology
Source: <https://www.510kdatabase.net/k191239/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Meter, Peak Flow, Spirometry (BZH)
Date received	May 8, 2019
Decision date	Dec 6, 2019
Days to decision	212 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Guangzhou Homesun Medical Technology Co., Ltd.
Location	Guangzhou, CN
Contact	Jinqun Li
510(k) history	2 submissions · 2 cleared · 2019-2024

REGULATORY CONSULTANT

Consulting firm	Feiyang Drug & Medical Consulting Technical Service Group
Contact	Tracy Che

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

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