FDA 510(k) Premarket Notification

K191239 Smart Peak Flow Meter

CLEARED

Dec 6, 2019
212 days to decision

K191239 · 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	**Feiying 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