FDA 510(k) Premarket Notification

# K231561 Pulmonary Function Tester, Model: A9

**CLEARED**

Feb 21, 2024
266 days to decision

K231561 · Product code: **BTY** · Anesthesiology
Source: https://www.510kdatabase.net/k231561/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Calculator, Predicted Values, Pulmonary Function (BTY) |
| Date received | May 31, 2023 |
| Decision date | Feb 21, 2024 |
| Days to decision | 266 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 | Suijie Huang |
| 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