

K231667 Withings Sleep RxSep 6, 2024
457 days to decisionK231667 · Product code: **MNR** · Anesthesiology
Source: <https://www.510kdatabase.net/k231667/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Ventilatory Effort Recorder (MNR) |
| Date received | Jun 7, 2023 |
| Decision date | Sep 6, 2024 |
| Days to decision | 457 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Withings |
| Location | Hsin Chu City, TW |
| Contact | Khushboo Surendran |
| Website | http://www.withings.com |
| 510(k) history | 7 submissions · 7 cleared · 2011-2025 |

Withings is a digital health company that designs and manufactures connected medical devices for consumer health monitoring. The company develops smart scales, wearable watches, blood pressure monitors, and specialized health tracking devices. Withings operates with a manufacturing facility in Hsin Chu City, Taiwan. The company has received FDA 510(k) clearances from total submissions, with no denied submissions on record. Cardiovascular devices represent 71% of submissions, reflecting the company's core focus on heart health monitoring and blood pressure management. With...