FDA 510(k) Premarket Notification

# K131994 SOMNOLYZER 24X7

**CLEARED**

Oct 17, 2013
111 days to decision

K131994 · Product code: **MNR** · Anesthesiology
Source: https://www.510kdatabase.net/k131994/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Ventilatory Effort Recorder (MNR) |
| Date received | Jun 28, 2013 |
| Decision date | Oct 17, 2013 |
| Days to decision | 111 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Respironics, Inc.** |
| Location | Monroeville, PA, US |
| Contact | DANIELA AIZPITARTE |
| Website | https://www.respironics.com |
| 510(k) history | 172 submissions · 168 cleared · 1977-2024 |

Respironics, Inc. is an American medical supply company owned by Philips. It specializes in products that improve respiratory functions and is based in Monroeville, Pennsylvania. The company maintains a strong FDA 510(k) regulatory record spanning from 1977 to 2024. Respironics has received FDA 510(k) clearances from total submissions. The dominant focus is Anesthesiology devices, which represent approximately 90% of all submissions. The latest clearance in 2024 reflects continued regulatory activity. Recent cleared devices include masks, ventilators, and sleep therapy sy...