

K012323 BIPAP SYNCHRONY VENTILATORY SUPPORT SYSTEM

Dec 20, 2001
150 days to decision

K012323 · Product code: **MNS** · Anesthesiology
Source: <https://www.510kdatabase.net/k012323/>

SUBMISSION DETAILS

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Ventilator, Continuous, Non-life-supporting (MNS) |
| Date received | Jul 23, 2001 |
| Decision date | Dec 20, 2001 |
| Days to decision | 150 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Respironics, Inc. |
| Location | Monroeville, PA, US |
| Contact | DAVID J VANELLA |
| 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...