

**K895351 RESPIRONICS INFANT BAGEASY**Oct 27, 1989  
56 days to decisionK895351 · Product code: **BTM** · Anesthesiology  
Source: <https://www.510kdatabase.net/k895351/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                 |
| Submission type       | Traditional  |
| Device classification | Ventilator, Emergency, Manual (resuscitator) (BTM) |
| Date received         | Sep 1, 1989  |
| Decision date         | Oct 27, 1989                                       |
| Days to decision      | 56 days  |
| Third-party review    | No   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Respironics, Inc.</b>  |
| Location       | Monroeville, PA, US   |
| Contact        | EUGENE SCARBERRY  |
| Website        | <a href="https://www.respironics.com">https://www.respironics.com</a> |
| 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...

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