

# K181170 Trilogy Evo Universal

Jul 18, 2019  
442 days to decision

K181170 · Product code: **CBK** · Anesthesiology  
Source: <https://www.510kdatabase.net/k181170/>

## SUBMISSION DETAILS

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)         |
| Submission type       | Traditional                                |
| Device classification | Ventilator, Continuous, Facility Use (CBK) |
| Date received         | May 2, 2018                                |
| Decision date         | Jul 18, 2019                               |
| Days to decision      | 442 days                                   |
| Third-party review    | No   |
| Summary / Statement   | Summary                                    |

## APPLICANT

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|                |   |
|----------------|---|
| Company        | <b>Respironics, Inc.</b>  |
| Location       | Monroeville, PA, US   |
| Contact        | Colleen Witt  |
| 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...