

**K833328 RESPIRONICS RESCUE DOME**Dec 16, 1983  
80 days to decisionK833328 · Product code: **CAE** · Anesthesiology  
Source: <https://www.510kdatabase.net/k833328/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Airway, Oropharyngeal, Anesthesiology (CAE)
Date received	Sep 27, 1983
Decision date	Dec 16, 1983
Days to decision	80 days
Third-party review	No

**APPLICANT**

---

Company	<b>Respironics, Inc.</b>
Location	Monroeville, PA, US
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...

---