

**K851396 SANDER'S MASKCPAP BY RESPIRONICS**May 15, 1985  
36 days to decisionK851396 · Product code: **BYE** · Anesthesiology  
Source: <https://www.510kdatabase.net/k851396/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Attachment, Breathing, Positive End Expiratory Pressure (BYE)
Date received	Apr 9, 1985
Decision date	May 15, 1985
Days to decision	36 days
Third-party review	No

**APPLICANT**

---

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

---