

K243394 AF531 Oro-Nasal SE Face MaskDec 30, 2024
60 days to decisionK243394 · Product code: **CBK** · Anesthesiology
Source: <https://www.510kdatabase.net/k243394/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Facility Use (CBK)
Date received	Oct 31, 2024
Decision date	Dec 30, 2024
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Respironics, Inc.
Location	Monroeville, PA, US
Contact	Gary LeMere
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...