

K150638 AF541 SE Full Face Mask

Sep 18, 2015
191 days to decision

K150638 · Product code: **CBK** · Anesthesiology
Source: <https://www.510kdatabase.net/k150638/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Ventilator, Continuous, Facility Use (CBK)
Date received	Mar 11, 2015
Decision date	Sep 18, 2015
Days to decision	191 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Respironics, Inc.
Location	Monroeville, PA, US
Contact	Shaylee Masilunas
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...