FDA 510(k) Premarket Notification

K001208 ESPIRT

CLEARED

May 12, 2000
28 days to decision

K001208 · Product code: **CBK** · Anesthesiology
Source: https://www.510kdatabase.net/k001208/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ventilator, Continuous, Facility Use (CBK)
Date received	Apr 14, 2000
Decision date	May 12, 2000
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Respironics, Inc.**
Location	Monroeville, PA, US
Contact	KATHY MOORE
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...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k001208/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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