FDA 510(k) Premarket Notification

K000994 BIPAP DUET LX BI-LEVEL SYSTEM

CLEARED

Jun 22, 2000
86 days to decision

K000994 · Product code: **BZD** · Anesthesiology
Source: https://www.510kdatabase.net/k000994/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Mar 28, 2000
Decision date	Jun 22, 2000
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Respironics, Inc.**
Location	Monroeville, PA, US
Contact	DAVID J VANELLA
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...