

**K990574 STICK-ON DISPOSABLE NASAL MASK, MODEL
312174, 1001964**May 24, 1999
90 days to decisionK990574 · Product code: MNT · Anesthesiology
Source: <https://www.510kdatabase.net/k990574/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - ST
Submission type	Traditional
Device classification	Ventilator, Continuous, Minimal Ventilatory Support, Facility Use (MNT)
Date received	Feb 23, 1999
Decision date	May 24, 1999
Days to decision	90 days
Third-party review	No

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...

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