FDA 510(k) Premarket Notification

K900113 RESPIRONICS' REMSTAR(TM) SLEEPEASY

CLEARED

Mar 28, 1990
78 days to decision

K900113 · Product code: **BYE** · Anesthesiology
Source: https://www.510kdatabase.net/k900113/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Attachment, Breathing, Positive End Expiratory Pressure (BYE)
Date received	Jan 9, 1990
Decision date	Mar 28, 1990
Days to decision	78 days
Third-party review	No

APPLICANT

Company	**Respironics, Inc.**
Location	Monroeville, PA, US
Contact	EUGENE N SCARBERRY
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...