FDA 510(k) Premarket Notification

K081029 SLEEPSTYLE 200 AUTO SERIES HC254

CLEARED

Sep 12, 2008
154 days to decision

K081029 · Product code: **BZD** · Anesthesiology
Source: https://www.510kdatabase.net/k081029/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Apr 11, 2008
Decision date	Sep 12, 2008
Days to decision	154 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Fisher &Paykel Healthcare , Ltd.**
Location	Auckland, New Zealand, NZ
Contact	JAMES THOMPSON
Website	https://www.fphcare.com/
510(k) history	70 submissions · 70 cleared · 1988-2025

Fisher &Paykel Healthcare, Ltd. is a medical device manufacturer based in Auckland, New Zealand. The company has driven innovation in healthcare technologies for over 50 years. Fisher &Paykel Healthcare has received FDA 510(k) clearances from total submissions since 1988. The company specializes in Anesthesiology devices, which represent 91% of its regulatory submissions. The latest clearance was granted in 2025, confirming active ongoing development. Recent cleared devices include high-flow nasal therapy systems, noninvasive ventilation masks, and respiratory support int...