FDA 510(k) Premarket Notification

K020332 RESPIRATORY HUMIDIFIER, MODEL MR850

CLEARED

Jul 7, 2003
522 days to decision

K020332 · Product code: **BTT** · Anesthesiology
Source: https://www.510kdatabase.net/k020332/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Humidifier, Respiratory Gas, (direct Patient Interface) (BTT)
Date received	Jan 31, 2002
Decision date	Jul 7, 2003
Days to decision	522 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Fisher &Paykel Healthcare , Ltd.**
Location	Auckland, New Zealand, NZ
Contact	BRETT WHISTON
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...