FDA 510(k) Premarket Notification

K881970 MODEL MR2000 HEATED RESPIRATORY HUMIDIFIER

CLEARED

Mar 9, 1989
302 days to decision

K881970 · Product code: **BTT** · Anesthesiology
Source: https://www.510kdatabase.net/k881970/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Humidifier, Respiratory Gas, (direct Patient Interface) (BTT)
Date received	May 11, 1988
Decision date	Mar 9, 1989
Days to decision	302 days
Third-party review	No

APPLICANT

Company	**Fisher &Paykel Healthcare , Ltd.**
Location	Auckland, New Zealand, NZ
Contact	DAVID MILBURN
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...

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Device record: https://www.510kdatabase.net/k881970/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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