FDA 510(k) Premarket Notification

CLEARED

K143646 MR810 System, 900MR810 Adult Single Limb Circuit, 900MR810E Adult Dual Limb Circuit

Mar 5, 2015
73 days to decision

K143646 · Product code: **BTT** · Anesthesiology
Source: https://www.510kdatabase.net/k143646/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Humidifier, Respiratory Gas, (direct Patient Interface) (BTT)
Date received	Dec 22, 2014
Decision date	Mar 5, 2015
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Fisher &Paykel Healthcare , Ltd.**
Location	Auckland, New Zealand, NZ
Contact	Elizabeth Goldstein
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...