

**K250651 OptiPAP Junior Flexi Tube US (OPTIPAPFUS)**Nov 19, 2025  
260 days to decisionK250651 · Product code: **SGR** · Anesthesiology  
Source: <https://www.510kdatabase.net/k250651/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Noninvasive Positive Airway Pressure System, Facility Use (SGR)
Date received	Mar 4, 2025
Decision date	Nov 19, 2025
Days to decision	260 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	OptiPAP Junior Nasal Prongs XXS (OPTIPAPPXXS); OptiPAP Junior Nasal Prongs XS (OPTIPAPPXS); OptiPAP Junior Nasal Prongs S (OPTIPAPPS); OptiPAP Junior Nasal Prongs M (OPTIPAPPM); OptiPAP Junior Nasal Prongs L (OPTIPAPPL); OptiPAP Junior Nasal Prongs XL (OPTIPAPPXL); OptiPAP Junior Nasal Mask XXS (OPTIPAPMXXS); OptiPAP Junior Nasal Mask XS (OPTIPAPMXS); OptiPAP Junior Nasal Mask S (OPTIPAPMS); OptiPAP Junior Nasal Mask M (OPTIPAPMM); OptiPAP Jun

**APPLICANT**

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Company	<b>Fisher &amp;Paykel Healthcare , Ltd.</b>
Location	Auckland, New Zealand, NZ
Contact	Reena Daken
Website	<a href="https://www.fphcare.com/">https://www.fphcare.com/</a>
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...