

K230483 Passy Muir Tracheostomy Viral & Bacterial Airway Protection Filter (PM-APF15)Sep 16, 2023
205 days to decisionK230483 · Product code: **CAH** · General Hospital
Source: <https://www.510kdatabase.net/k230483/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filter, Bacterial, Breathing-circuit (CAH)
Date received	Feb 23, 2023
Decision date	Sep 16, 2023
Days to decision	205 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Passy-Muir, Inc.
Location	Irvine, CA, US
Contact	Donna Malter
510(k) history	5 submissions · 5 cleared · 1995-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230483/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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