

K173918 VersaPAP Positive Airway Pressure (PAP) DeviceAug 17, 2018
238 days to decisionK173918 · Product code: **BWF** · AnesthesiologySource: <https://www.510kdatabase.net/k173918/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Therapeutic (incentive) (BWF)
Date received	Dec 22, 2017
Decision date	Aug 17, 2018
Days to decision	238 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Trudell Medical International
Location	London, CA
Contact	Marianne Tanton
510(k) history	9 submissions · 9 cleared · 2015-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k173918/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026