

K183108 Combined Aerobika OPEP and VersaPAP deviceAug 16, 2019
281 days to decisionK183108 · Product code: **BWF** · AnesthesiologySource: <https://www.510kdatabase.net/k183108/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Therapeutic (incentive) (BWF)
Date received	Nov 8, 2018
Decision date	Aug 16, 2019
Days to decision	281 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

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