

K203209 AirPhysio Positive Expiratory Pressure (PEP) DeviceJan 15, 2021
77 days to decisionK203209 · Product code: **BYI** · Anesthesiology
Source: <https://www.510kdatabase.net/k203209/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Percussor, Powered-electric (BYI)
Date received	Oct 30, 2020
Decision date	Jan 15, 2021
Days to decision	77 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Airphysio Pty, Ltd.
Location	Tweed Heads South, AU
Contact	Paul O'Brien
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Accelerated Device Approval Services
Contact	Rafael Aguila

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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