

K133051 PULMONE MINIBOX PFT TMMay 2, 2014
217 days to decisionK133051 · Product code: **BZC** · Anesthesiology
Source: <https://www.510kdatabase.net/k133051/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calculator, Pulmonary Function Data (BZC)
Date received	Sep 27, 2013
Decision date	May 2, 2014
Days to decision	217 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Pulmone Advanced Medical Devices, Ltd.
Location	Gaithersburg, MD, US
Contact	Rhona Shanker
510(k) history	3 submissions · 3 cleared · 2014-2016

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