

K141793 PULMONE MINIBOXPFT 2.0Mar 6, 2015
247 days to decisionK141793 · Product code: **BZG** · Anesthesiology
Source: <https://www.510kdatabase.net/k141793/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Diagnostic (BZG)
Date received	Jul 2, 2014
Decision date	Mar 6, 2015
Days to decision	247 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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