

K150044 O-PEPMay 27, 2016
501 days to decisionK150044 · Product code: **BWF** · Anesthesiology
Source: <https://www.510kdatabase.net/k150044/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Therapeutic (incentive) (BWF)
Date received	Jan 12, 2015
Decision date	May 27, 2016
Days to decision	501 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Pari Respiratory Equipment, Inc.
Location	Midlothian, VA, US
Contact	Michael Judge
510(k) history	10 submissions · 10 cleared · 2009-2025

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