

K160636 iPEP System and vPEPAug 3, 2016
149 days to decisionK160636 · Product code: **BWF** · Anesthesiology
Source: <https://www.510kdatabase.net/k160636/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Therapeutic (incentive) (BWF)
Date received	Mar 7, 2016
Decision date	Aug 3, 2016
Days to decision	149 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	D R Burton Healthcare, LLC
Location	Farmville, NC, US
Contact	DENNIS COOK
510(k) history	2 submissions · 2 cleared · 2016-2020

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