FDA 510(k) Premarket Notification

K153441 VibraPEP

CLEARED

Mar 25, 2016
119 days to decision

K153441 · Product code: **BWF** · Anesthesiology
Source: https://www.510kdatabase.net/k153441/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Therapeutic (incentive) (BWF)
Date received	Nov 27, 2015
Decision date	Mar 25, 2016
Days to decision	119 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medica Holdings, LLC**
Location	Lake Oswego, OR, US
Contact	George Reed
510(k) history	3 submissions · 3 cleared · 2016-2018