

K181660 Acapella Choice Blue Vibratory PEP DeviceOct 24, 2019
486 days to decisionK181660 · Product code: **BWF** · Anesthesiology
Source: <https://www.510kdatabase.net/k181660/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Therapeutic (incentive) (BWF)
Date received	Jun 25, 2018
Decision date	Oct 24, 2019
Days to decision	486 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Smiths Medical
Location	Hythe, Kent, GB
Contact	Donna Semlak
Website	http://www.smiths-medical.com/
510(k) history	3 submissions · 3 cleared · 2004-2019

REGULATORY CONSULTANT

Consulting firm	Mrc-X, LLC
Contact	Dawn Norman

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181660/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026