FDA 510(k) Premarket Notification

K181660 Acapella Choice Blue Vibratory PEP Device

CLEARED

Oct 24, 2019
486 days to decision

K181660 · 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