FDA 510(k) Premarket Notification

K162131 ExSpiron 1Xi

CLEARED

May 9, 2017
281 days to decision

K162131 · Product code: **BZK** · Anesthesiology
Source: https://www.510kdatabase.net/k162131/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Monitoring (w/wo Alarm) (BZK)
Date received	Aug 1, 2016
Decision date	May 9, 2017
Days to decision	281 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Respiratory Motion, Inc.**
Location	Waltham, MA, US
Contact	Edwin Rule
510(k) history	4 submissions · 4 cleared · 2012-2018