

K192595 ExSpiron 2XiDec 17, 2019
88 days to decisionK192595 · Product code: **BZK** · Anesthesiology
Source: <https://www.510kdatabase.net/k192595/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Spirometer, Monitoring (w/wo Alarm) (BZK)
Date received	Sep 20, 2019
Decision date	Dec 17, 2019
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Respiratory Motion
Location	Watertown, MA, US
Contact	Susan K. Hamann
510(k) history	1 submissions · 1 cleared · 2019-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192595/> 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 20, 2026