FDA 510(k) Premarket Notification

K202837 GoSpiro

CLEARED

Dec 4, 2020
70 days to decision

K202837 · Product code: **BZG** · Anesthesiology
Source: https://www.510kdatabase.net/k202837/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Spirometer, Diagnostic (BZG)
Date received	Sep 25, 2020
Decision date	Dec 4, 2020
Days to decision	70 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Monitored Therapeutics, Inc.**
Location	Dublin, OH, US
Contact	Michael Taylor
510(k) history	2 submissions · 2 cleared · 2017-2020

REGULATORY CONSULTANT

Consulting firm	**Monitored Therapeutics, Inc. C/O Promedic, LLC**
Contact	Paul Dryden

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov