

K200076 Breezing MedSep 25, 2020
255 days to decisionK200076 · Product code: **BZL** · Anesthesiology
Source: <https://www.510kdatabase.net/k200076/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Oxygen-uptake (BZL)
Date received	Jan 14, 2020
Decision date	Sep 25, 2020
Days to decision	255 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tf Health Co.
Location	Tempe, AZ, US
Contact	Erik Herrmann
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Nda Partners
Contact	Roberta (Bobbi) Druyor-Sanchez

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200076/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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