FDA 510(k) Premarket Notification

CLEARED

K202480 Nitronox Plus 0-70, Nitronox 0-50, Nitronox Plus 50/50

Apr 22, 2021
237 days to decision

K202480 · Product code: **BZR** · Anesthesiology
Source: https://www.510kdatabase.net/k202480/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mixer, Breathing Gases, Anesthesia Inhalation (BZR)
Date received	Aug 28, 2020
Decision date	Apr 22, 2021
Days to decision	237 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Parker Hannifin**
Location	Hatfield, PA, US
Contact	Andrew Ellinger
Website	http://www.parker.com/
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**Third Party Review Group, LLC**
Contact	Dave Yungvirt

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