FDA 510(k) Premarket Notification

CLEARED

K250322 Respond OC Conserving Regulator (130-0800)

Jul 24, 2025
170 days to decision

K250322 · Product code: **NFB** · Anesthesiology
Source: https://www.510kdatabase.net/k250322/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Conserver, Oxygen (NFB)
Date received	Feb 4, 2025
Decision date	Jul 24, 2025
Days to decision	170 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Responsive Respiratory**
Location	St. Louis, MO, US
Contact	Steve Bannon
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**ProMedic, LLC**
Contact	Paul Dryden

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