

K220591 ProximaDec 15, 2022
289 days to decisionK220591 · Product code: **NFB** · Anesthesiology
Source: <https://www.510kdatabase.net/k220591/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Conserver, Oxygen (NFB)
Date received	Mar 1, 2022
Decision date	Dec 15, 2022
Days to decision	289 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dynasthetics, LLC
Location	Salt Lake City, UT, US
Contact	Joseph Orr
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	ProMedic Consulting, LLC
Contact	Paul Dryden

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

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