

K200401 ApogeeNov 14, 2020
270 days to decisionK200401 · Product code: **NFB** · Anesthesiology
Source: <https://www.510kdatabase.net/k200401/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Conserver, Oxygen (NFB)
Date received	Feb 18, 2020
Decision date	Nov 14, 2020
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Incoba Ltd D/B/A Dynaris
Location	Chesterfield, MO, US
Contact	Lon Aylsworth
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Incoba Ltd D/B/A Dynaris % Promedic, LLC
Contact	Paul Dryden

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

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