FDA 510(k) Premarket Notification

K200401 Apogee

CLEARED

Nov 14, 2020
270 days to decision

K200401 · 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