FDA 510(k) Premarket Notification

CLEARED

K221014 Effortless Oxygen Conserver System Models Effortless Pro and Effortless Mobile

Oct 17, 2022
195 days to decision

K221014 · Product code: **NFB** · Anesthesiology
Source: https://www.510kdatabase.net/k221014/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Conserver, Oxygen (NFB)
Date received	Apr 5, 2022
Decision date	Oct 17, 2022
Days to decision	195 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Effortless Oxygen, LLC**
Location	Phoenix, AZ, US
Contact	Samir Ahmad
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Effortless Oxygen., LLC C/O Promedic, LLC**
Contact	Paul Dryden

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