FDA 510(k) Premarket Notification

K203343 Wesper Lab

CLEARED

Dec 21, 2021
403 days to decision

K203343 · Product code: **MNR** · Anesthesiology
Source: https://www.510kdatabase.net/k203343/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Nov 13, 2020
Decision date	Dec 21, 2021
Days to decision	403 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Wesper, Inc.**
Location	New York, NY, US
Contact	Amir Reuveny
Website	https://wesper.co
510(k) history	4 submissions · 4 cleared · 2021-2026