FDA 510(k) Premarket Notification

K220012 BresoDX1

CLEARED

Dec 21, 2022
351 days to decision

K220012 · Product code: **MNR** · Anesthesiology
Source: https://www.510kdatabase.net/k220012/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Jan 4, 2022
Decision date	Dec 21, 2022
Days to decision	351 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Bresotec, Inc.**
Location	Toronto, CA
Contact	Esther Sur
510(k) history	1 submissions · 1 cleared · 2022-2022

CLINICAL EVIDENCE - NCT04897399

[Trial of device that is not approved or cleared by the U.S. FDA]

Status	Withheld - *No results published to ClinicalTrials.gov*
Sponsor	[Redacted]

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04897399