FDA 510(k) Premarket Notification

K243268 TipTraQ (TTQ001)

CLEARED

Feb 3, 2025
111 days to decision

K243268 · Product code: **MNR** · Anesthesiology
Source: https://www.510kdatabase.net/k243268/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Oct 15, 2024
Decision date	Feb 3, 2025
Days to decision	111 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Pranaq Pte. , Ltd.**
Location	Singapore, SG
Contact	Jerry Chen
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Medignite Consulting, LLC**
Contact	Amy Herder

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

CLINICAL EVIDENCE - NCT06351878

TipTraQ Home Sleep Test Validation Study, Duke

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	200 patients (actual)
Study sites	1 site
Condition studied	Obstructive Sleep Apnea
Study type	Observational
Completion date	Aug 23, 2024
Sponsor	PranaQ Pte. Ltd. (Industry)

Primary outcome

Apnea Hypopnea Index(AHI)

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT06351878