February 3, 2025

PranaQ Pte. Ltd.
% Amy Herder
Founder & Principal Consultant
MedIgnite Consulting, LLC
1709 Saracen Rd
Austin, Texas 78733

Re: K243268
Trade/Device Name: TipTraQ (TTQ001)
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: MNR
Dated: October 15, 2024
Received: January 3, 2025

Dear Amy Herder:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Rachana Visaria -S

Rachana Visaria, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243268

Device Name

TipTraQ (TTQ001)

Indications for Use *(Describe)*

The TipTraQ is a wearable device intended for aiding in sleep apnea evaluation/diagnosis for adult patients suspected of sleep apnea in both home-based and clinical-use environments.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary

[Prepared in accordance with 21 CFR 807.92]

Date: February 3, 2025

I. CONTACT DETAILS

Submitter: PranaQ Pte. Ltd.
331 NORTH BRIDGE ROAD, #12 - 03 ODEON TOWERS, SINGAPORE 188720

+65 3158 4380
Contact Name: Jerry Chen
jerry.chen@pranaq.com

II. DEVICE NAME

Device Name: TipTraQ (TTQ001)
Common Name: Breathing frequency monitor
Classification: Ventilatory Effort Recorder
Regulation: 21 CFR 868.2375
Product Code: MNR

III. PREDICATE

Predicate Device(s): K220028, NightOwl **(Primary)**
K222579, Belun Sleep System BLS-100 (Reference Device)
K231355, EnsoSleep PPG (formerly Aurora) (Reference Device)

IV. DEVICE DESCRIPTION SUMMARY

TipTraQ is a prescription-only medical device aiding in sleep apnea evaluation/diagnosis comprising a fingertip wearable device, a companion mobile app, a cloud-based AI analysis and an information display system. It collects essential physiological waveform information, including Photoplethysmogram (PPG) and accelerometer data. The TipTraQ Algorithm System determines Total Sleep Time (TST), Total REM Time (TREMT), Oxygen Desaturation Index (ODI), and Apnea-Hypopnea Index (AHI) from the recorded waveform signals.

TipTraQ Sensor includes a PPG sensor, which uses light sources (green, red, and infrared) and two photodetectors to measure the blood volume changes in the microvascular bed of tissue. Additionally, the TipTraQ Sensor utilizes an Inertial Measurement Unit (IMU) with three-axis accelerometers (device-function) and three-axis gyroscopes (non-device function), monitoring movement and actigraphy to assess sleep stages. The TipTraQ Expert Panel can display recorded physiological waveforms, while the TipTraQ API System generates output for essential physiological parameters analyzed by the TipTraQ Algorithm System.

The TipTraQ Sensor is rechargeable and designed to provide at least 12 hours of usage after fully charged. The TipTraQ Charging Case, which is also rechargeable, provides a battery capacity of eight full charges of the TipTraQ Sensor for user convenience. The TipTraQ Charging Case can be powered and charged using an external USB-C.

V. INTENDED USE / INDICATIONS FOR USE

The TipTraQ is a wearable device intended for aiding in sleep apnea evaluation/diagnosis for adult patients suspected of sleep apnea in both home-based and clinical-use environments.

VI. COMPARISON OF INDICATIONS & TECHNOLOGICAL CHARACTERISTICS

Characteristic	TipTraQ, K243268 (Subject Device)	NightOwl, K220028 (Primary Predicate)	Belun Sleep System BLS-100, K222579 (Reference Device 1)	EnsoSleep PPG (formerly Aurora), K231355 (Reference Device 2)
Intended Use/ Indications for Use	The TipTraQ is a wearable device intended for aiding in sleep apnea evaluation/diagnosis for adult patients suspected of sleep apnea in both home-based and clinical-use environments.	The NightOwl is a wearable device intended for use in the recording, analysis, displaying, exporting, and storage of biophysical parameters to aid in the evaluation of sleep-related breathing disorders of adult patients suspected of sleep apnea. The device is intended for the clinical and home setting use under the direction of a Healthcare Professional (HCP).	The Belun Sleep System BLS-100 is a wearable device intended to record, analyze, display, export, and store biophysical parameters to aid in evaluating moderate to severe sleep-related breathing disorders of adult patients suspected of sleep apnea. The device is intended for use in clinical and home settings under the direction of a Healthcare Professional (HCP).	Aurora is a Software as a Medical Device (SaMD) that establishes sleep quality. Aurora automatically analyzes, displays, and summarizes Photoplethysmogram (PPG) data collected during sleep. Aurora is intended for use by and by order of a healthcare professional to aid in the diagnosis of sleep disorders including sleep apnea in adults. The Aurora output, including automatically detected respiratory events and parameters, may be displayed and edited by a qualified healthcare professional. The Aurora output is not intended to be interpreted or clinical action taken without

Characteristic	TipTraQ, K243268 (Subject Device)	NightOwl, K220028 (Primary Predicate)	Belun Sleep System BLS-100, K222579 (Reference Device 1)	EnsoSleep PPG (formerly Aurora), K231355 (Reference Device 2)
				consultation of a qualified healthcare professional. Aurora is not intended for use with polysomnography devices.
Intended Environment	Recording in the home environment or clinical environment with the report interpretation performed in the clinical setting.	Recording in the home environment with the report interpretation performed in the clinical setting.	Recording in the home environment with the report interpretation performed in the clinical setting.	N/A (Software)
Prescription	Prescription only	Prescription only	Prescription only	Prescription only
Target Population	22 years old and older	22 years old and older	22 years old and older	Adults
Channels	1. Photoplethysmography (PPG) 2. Pulse rate 3. Oximetry 4. Actigraphy	1. PAT 2. Pulse rate 3. Oximetry 4. Actigraphy	1. Photoplethysmography (PPG) 2. Pulse rate 3. Oximetry 4. Actigraphy	1. Photoplethysmography (PPG) 2. Oximetry

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Sensors	Optical plethysmography sensor (Red, Infrared Red, Green), accelerometer	Optical plethysmography sensor (Red, Infrared Red), accelerometer	Optical plethysmography sensor (Red, Infrared Red), accelerometer	N/A (Software)
Wearable sensor location	The photoplethysmography (PPG) sensor and accelerometer components are worn on the fingertip.	The photoplethysmography (PPG) sensor and accelerometer components are worn on the fingertip.	The photoplethysmography (PPG) sensor and accelerometer components are worn on the proximal phalanx of index finger.	N/A (Software)
Sensor Software	Firmware is limited to control the recording and communications processes. Presentation of test results to the patient only after confirmed by HCP. Data analyzed and presented in a separate software suite.	Firmware is limited to control the recording and communications processes. No presentation of test results to the patient. Data analyzed and presented in a separate software suite.	Firmware is limited to control the recording and communications processes. No presentation of test results to the patient. Data analyzed and presented in a separate software suite.	N/A (Software)
Analysis Software - location	Analysis performed off the recording device, exclusively cloud-based by the TipTraQ software.	Analysis performed off the recording device, exclusively cloud-based by the NightOwl software.	Analysis performed off the recording device, exclusively stand-alone by the Belun software.	Analysis performed off the recording device, exclusively cloud-based by the EnsoSleep software.

Characteristic	TipTraQ, K243268 (Subject Device)	NightOwl, K220028 (Primary Predicate)	Belun Sleep System BLS-100, K222579 (Reference Device 1)	EnsoSleep PPG (formerly Aurora), K231355 (Reference Device 2)
Analysis Software - algorithm- AHI	TQ-AHI calculation tuned to the AASM's '1A Rule' for the scoring of hypopnea AND TQ-AHI calculation tuned to the AASM's '1B Rule' for the scoring of hypopnea	pAHI calculation tuned to the AASM's '1A Rule' for the scoring of hypopnea AND pAHI calculation tuned to the AASM's '1B Rule' for the scoring of hypopnea	bAHI calculation tuned to the AASM's '1B Rule' for the scoring of hypopnea	N/A
Analysis Software - algorithm - Sleep Time	Total Sleep Time (TQ-TST) calculation, and, Total REM Time (TQ-TREMT) calculation	Total Sleep Time (TST) calculation, and, Total REM Time calculation	bTST calculation (time summation of REM and NREM stages)	N/A
Analysis Software - algorithm - Sleep Stage	Sleep Stages (Wake, REM, NREM)	N/A	bSTAGES: WAKE, NREM and REM	N/A

Characteristic	TipTraQ, K243268 (Subject Device)	NightOwl, K220028 (Primary Predicate)	Belun Sleep System BLS-100, K222579 (Reference Device 1)	EnsoSleep PPG (formerly Aurora), K231355 (Reference Device 2)
Data transfer	Data transfer through a smartphone by wireless connection.	Data transfer through a smartphone by wireless connection.	Data transfer by physical or wireless connection.	N/A (Software)
Power Source recorder	Internal rechargeable li-ion battery	Battery powered by coin cell	3.7V Lithium Battery	N/A (Software)
Patient Isolation	Device has no galvanic connections to mains as it is a battery-operated device.	Device has no galvanic connections to mains as it is a battery-operated device.	N/A	N/A (Software)
Sterilization	Non-sterile	Non-sterile	N/A	N/A (Software)
Material(s) in primary contact	1. PC 2. Silicone rubber 3. Nylon-based fabric	1. Biocompatible polyethylene foam and polyester film with acrylic adhesive layer	1. TPE 2. PC	N/A (Software)

Characteristic	TipTraQ, K243268 (Subject Device)	NightOwl, K220028 (Primary Predicate)	Belun Sleep System BLS-100, K222579 (Reference Device 1)	EnsoSleep PPG (formerly Aurora), K231355 (Reference Device 2)
Contact duration (biocompatibility)	Prolonged duration (>24 hours to 30 days), cumulatively	Limited duration (Up to 24 hours)	Prolonged duration (>24 hours to 30 days), cumulatively	N/A (Software)
Bio-compatibility	Assessed to ISO 10993-1:2018	Assessed to ISO 10993-1:2009 requirements for sensitization, irritation, and cytotoxicity	Tested in accordance to ISO 10993-1:2018 for sensitization, irritation, and cytotoxicity	N/A (Software)
EMC	IEC 60601-1-2:2014 +AMD1:2020	IEC 60601-1-2:2014	IEC 60601-1-2:2014	N/A (Software)
Electrical Safety	IEC 60601-1:2005 +A1:2012+A2:2020	IEC 60601-1:2005 +AMD1:2012	IEC 60601-1:2005 +A1:2012	N/A (Software)
Environmental Testing	IEC 60601-1-11:2015 + A1:2020	IEC 60601-1-11:2010	IEC 60601-1-11:2015	N/A (Software)

Characteristic	TipTraQ, K243268 (Subject Device)	NightOwl, K220028 (Primary Predicate)	Belun Sleep System BLS-100, K222579 (Reference Device 1)	EnsoSleep PPG (formerly Aurora), K231355 (Reference Device 2)
Output parameters	1. TQ-AHI 2. Total Sleep Time 3. Total REM Time 4. Sleep Stages (Wake, REM, NREM) 5. Sleep Efficiency 6. Sleep Latency 7. Wake After Sleep Onset 8. SpO2 (min, max) 9. ODI 3%, ODI 4% 10. T90 11. Pulse Rate (PR) (mean, PR > 100 bpm, PR < 40 bpm)	1. pAHI 2. Total Sleep Time 3. Total REM Time 4. SpO2 (min, max) 5. ODI 3%, ODI 4% 6. T90, T88 7. Pulse Rate (PR) (mean, PR > 100 bpm, PR < 40 bpm, Min, Max)	1. bAHI 2. Total Sleep Time 3. Sleep Stages (Wake, REM, NREM) 4. SpO2 5. Pulse Rate 6. Low Perfusion	1. eAHI 2. Total Sleep Time 3. Sleep Stages 4. Sleep Efficiency 5. Sleep latency 6. Wake After Sleep Onset 7. ODI
AHI Performance Using AASM 1a Rule				
AHI 1a cutoff = 5	Sensitivity: 0.868 Specificity: 0.741	Sensitivity: 0.936 Specificity: 0.727	N/A	Sensitivity: 0.926 Specificity: 0.716
AHI 1a cutoff = 15	Sensitivity: 0.876 Specificity: 0.755	Sensitivity: 0.978 Specificity: 0.704	N/A	N/A

Characteristic	TipTraQ, K243268 (Subject Device)	NightOwl, K220028 (Primary Predicate)	Belun Sleep System BLS-100, K222579 (Reference Device 1)	EnsoSleep PPG (formerly Aurora), K231355 (Reference Device 2)
AHI 1a cutoff = 30	Sensitivity: 0.806 Specificity: 0.905	Sensitivity: 0.964 Specificity: 0.844	N/A	N/A
AHI Performance Using AASM 1b Rule				
AHI 1b cutoff = 5	Sensitivity: 0.924 Specificity: 0.801	Sensitivity: 1.000 Specificity 0.823	N/A	Sensitivity: 0.894 Specificity: 0.768
AHI 1b cutoff = 15	Sensitivity: 0.909 Specificity: 0.908	Sensitivity: 0.973 Specificity: 0.886	Sensitivity: 0.898 Specificity: 0.860	N/A
AHI 1b cutoff = 30	Sensitivity: 1.000 Specificity: 0.933	Sensitivity: 0.840 Specificity: 0.979	Sensitivity: 0.840 Specificity: 0.951	N/A
Oximetry Performance				
SpO2 Accuracy (Overall Arms)	1.41	2.69	2.7	N/A (Software)
PR Range	40-200 bpm	50-118 bpm	30-250 bpm	N/A (Software)
PR Accuracy (Arms)	1.04	2.26	± 2.5 bpm or 2% whichever larger	N/A (Software)

VII. NON-CLINICAL PERFORMANCE TESTS

The following performance tests were conducted in support the substantial equivalence determination:

Bench testing
Testing was conducted to provide verification of pulse rate between 40 to 200 BPM using a multifunctional testing unit in accordance with ISO 80601-2-61:2019.

Software verification & validation (V&V)
Software V&V was conducted in accordance with FDA guidance, *Content of Premarket Submission for Device Software Functions, Guidance for Industry and Food and Drug Administration Staff*.

Electrical, Mechanical, Thermal, and electromagnetic compatibility (EMC)
Testing was conducted in accordance with the following FDA recognized consensus standards to support the electrical, mechanical, thermal safety, and electromagnetic compatibility (EMC) of the device.

- IEC 60601-1:2020 *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*- with US national differences
- IEC 60601-1-2:2014 +AMD1:2021 *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*
- IEC 60601-1-11:2020 *Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*
- IEC 62133-2:2017 *Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells and for batteries made from them for use in portable applications - Part 2: Lithium systems*

Biocompatibility evaluation
A biocompatibility assessment of TipTraQ has been conducted per ISO 10993-1:2018 and FDA Guidance on the Use of International Standard ISO 10993-1.

VII. CLINICAL PERFORMANCE TESTS

SpO2 validation study
An SpO2 validation study at University of California San Francisco (UCSF) was conducted in accordance with the FDA guidance, *Pulse Oximeters- Premarket Notification Submissions [510(k)s], Guidance for Industry and Food and Drug Administration Staff* and Annex EE.2 of ISO 80601-2-61:2019. The study included 12 subjects with a range of skin pigmentation, and

compared the TipTraQ sensor performance to reference arterial blood gas sampling over the range of 70 to 100%. The resulting Average Root Mean Square (Arms) error was 1.41, which met the predefined acceptance criteria <3.5. Pulse rate validation was also conducted over a range of 56-118 bpm and Arms of 1.64 was obtained. Please see the following table for a brief performance summary of the TipTraQ device.

SpO2 Accuracy

SaO2 range:	70-100% (Overall)	60-70%	70-80%	80-90%	90-100%
TipTraQ Arms	1.41	1.55	1.7	1.35	1.11

Sleep validation study

A clinical validation study was conducted at Duke University Hospital, which compared the performance of the TipTraQ device to the gold standard in-lab polysomnography (PSG). The study eventually included 147 qualified samples with representative demographics and met all the predetermined acceptance criteria (set by prior studies and reference literatures). Please see the table below for a brief performance summary of the TipTraQ device.

Measure	Metric		Result
Total Sleep Time	PCC		0.786
Epoch-wise Sleep Stage	Wake (0)	sensitivity	0.655
		specificity	0.901
		accuracy	0.837
	REM (1)	sensitivity	0.713
		specificity	0.930
		accuracy	0.905
	NREM (2)	sensitivity	0.824
		specificity	0.738

Measure	Metric		Result
		accuracy	0.791
AHI based on 1a rule	AHI cutoff 5	sensitivity	0.868
		specificity	0.741
	AHI cutoff 15	sensitivity	0.876
		specificity	0.755
	AHI cutoff 30	sensitivity	0.806
		specificity	0.905
AHI based on 1b rule	AHI cutoff 5	sensitivity	0.924
		specificity	0.801
	AHI cutoff 15	sensitivity	0.909
		specificity	0.908
	AHI cutoff 30	sensitivity	1.000
		specificity	0.933

VIII. CONCLUSIONS

In conclusion, there are minor differences in the indications for use statements and technological characteristics. These differences do not alter the intended use of the device as an aid in the evaluation of sleep apnea, nor do they raise different questions of safety or effectiveness compared to the predicate device. The non-clinical and clinical performance testing referenced in the 510(k) submission support the conclusion that the device is substantially equivalent to the predicate device.