June 27, 2026

Honeynaps co,. Ltd.
Young Jun Lee
Chief Executive Officer
4F, Marin B/D, 529, Nonhyeon-ro, Gangnam-gu
Seoul, 06126
Republic Of Korea

Re: K253390
Trade/Device Name: Somnum (somnum)
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLZ
Dated: May 25, 2026
Received: May 26, 2026

Dear Young Jun Lee:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Patrick Antkowiak -S

for
Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
Neurodiagnostic Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253390

Please provide the device trade name(s).

SOMNUM (SOMNUM)

Please provide your Indications for Use below.

SOMNUM is an AI-enabled software program intended for use as an aid in the diagnosis of sleep and respiratory-related sleep disorders. SOMNUM is intended to be used for analysis — including automatic scoring using AI/ML algorithms for sleep stage classification, arousal detection, respiratory event detection, and leg movement event detection, as well as manual scoring/re-scoring, display, redisplay (retrieve), summarization, and report generation of digital data collected by monitoring devices typically used to evaluate sleep and respiratory-related sleep disorders.
The device is to be used under the supervision of a physician. Use is restricted to data obtained from adult patients.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary

1. Submitter Information

Submitter	Name	Honeynaps
	Address	529, Nonhyeon-ro, Gangnam-gu, Seoul, Republic of Korea 06126
	Tel	+82-2-567-0134
Contact Person	Name	Young Jun Lee
	Title	CEO (Chief Executive Officer)
	Email	Tony.lee@honeynaps.com
Primary Contact Person	Name	Joo Hoon Song
	Title	Team Leader / Quality Innovation Team
	Email	James.song@honeynaps.com

2. Subject Device Information

Trade Name	SOMNUM
Common Name	Sleep Analysis System
Regulation Number	21 CFR 882.1400
Regulation Name	Electroencephalograph
Regulation Class	II
Classification Product Code	OLZ
Device Classification Name	Automatic Event Detection Software for Polysomnography with Electroencephalography
Review Panel	Neurology

3. Predicated Device and Reference Device Information

3.1 Predicated Device

510(k) Number	K223922
Applicant	Honeynaps Co., Ltd
Device Name	SOMNUM (V.1.1.2.)

Regulation Number	21 CFR 882.1400
Regulation Name	Electroencephalograph
Regulation Class	II
Classification Product Code	OLZ
Device Classification Name	Automatic Event Detection Software for Polysomnography with Electroencephalography

3.2 Reference Device 1

510(k) Number	K210034
Applicant	EnsoData, Inc
Device Name	EnsoSleep
Regulation Number	21 CFR 882.1400
Regulation Name	Electroencephalograph
Regulation Class	II
Classification Product Code	OLZ
Device Classification Name	Automatic Event Detection Software for Polysomnography with Electroencephalography

3.3 Reference Device 2

510(k) Number	K112102
Applicant	YOUNES SLEEP TECHNOLOGIES
Device Name	MICHELE SLEEP SCORING SYSTEM
Regulation Number	21 CFR 868.2375
Regulation Name	Beathing frequency monitor
Regulation Class	II
Classification Product Code	MNR
Device Classification Name	ventilatory effort recorder

4. Device Description

SOMNUM is an AI-enabled stand-alone software application that analyzes previously recorded physiological data obtained during level 1 sleep studies from adults (polysomnography, PSG records). SOMNUM automatically detects events and displays scoring results using artificial intelligence (AI)–based algorithms across all functional modules. Physicians can review, edit, or delete auto-scored events and generate a sleep summary report, which includes tables and graphs used for clinical assessment of sleep disorders.

Automated AI algorithms are applied to raw signals to identify specific events. In particular, the Sleep Stage Classification module, the Arousal Detection module, the Respiratory Event Detection module, and the Leg Movement Detection module are all powered by AI/ML algorithms. The software automates recognition of the following events:

- Sleep Stage Classification (AI/ML-based): Wake, N1, N2, N3, REM
- Arousal Event (AI/ML-based): Arousal
- Respiratory Events (AI/ML-based): Apnea, Hypopnea
- Apnea subclassification (Rule-based): Obstructive, Central, Mixed
- Leg Movement Event (AI/ML-based): Periodic Leg Movements during Sleep (PLMs)

5. Indications for Use

SOMNUM is an AI-enabled software program intended for use as an aid in the diagnosis of sleep and respiratory-related sleep disorders. SOMNUM is intended to be used for analysis — including automatic scoring using AI/ML algorithms for sleep stage classification, arousal detection, respiratory event detection, and leg movement event detection, as well as manual scoring/re-scoring, display, redisplay (retrieve), summarization, and report generation of digital data collected by monitoring devices typically used to evaluate sleep and respiratory-related sleep disorders.

The device is to be used under the supervision of a physician. Use is restricted to data obtained from adult patients.

6. Comparison of Technological Characteristics to the Predicated Device

	Result	Subject Device	Predicated Device	Reference Device 1	Reference Device 2
General Information					
Trade Name	-	SOMNUM	SOMNUM	EnsoSleep	MICHELE SLEEP SCORING SYSTEM
510(k) Number	-	K253390	K223922	K210034	K112102
510(k) Submitter	-	Honeynaps	Honeynaps	EnsoData, Inc	YOUNES SLEEP TECHNOLOGIES
Classification Product Code	-	OLZ	OLZ	OLZ	MNR
Indication for Use	Same	SOMNUM is an AI-enabled software program intended for use as an aid in the diagnosis of sleep and respiratory-related sleep disorders. SOMNUM is intended to be used for analysis — including automatic scoring using AI/ML	SOMNUM is a computer program (software) intended for use as an aid for the diagnosis of sleep and respiratory related sleep disorders. SOMNUM is intended to be used for analysis (automatic scoring and manual re-scoring), display,	EnsoSleep is intended for use in the diagnostic evaluation by a physician to assess sleep quality and as an aid for physicians in the diagnosis of sleep disorders and respiratory related sleep disorders in pediatric and adult patients as follows:	The MICHELE Sleep Scoring System is a computer program (software) intended for use as an aid for the diagnosis of sleep and respiratory related sleep disorders. The MICHELE Sleep Scoring System is intended to be used for analysis

		algorithms for sleep stage classification, arousal detection, respiratory event detection, and leg movement event detection, as well as manual scoring/re-scoring, display, redisplay (retrieve), summarization, and report generation of digital data collected by monitoring devices typically used to evaluate sleep and respiratory-related sleep disorders. The device is to be used under the supervision of a	redisplay(retrieve), summarize, reports generation of digital data collected by monitoring devices typically used to evaluate sleep and respiratory related sleep disorders. The device is to be used under the supervision of a physician Use is restricted to files obtained from adults' patients.	•Pediatric patients ages 13 years and older with polysomnography (PSG) tests obtained in a Hospital or Sleep Clinic •Adult patients with PSGs obtained in a Hospital or Sleep Clinic •Adult patients with Home Sleep Tests EnsoSleep is a softwareonly medical device to be used under the supervision of a clinician to analyze physiological signals and automatically score sleep study results, including the staging of sleep, detection of arousals, leg movements, and sleep disordered breathing events including	(automatic scoring and manual re-scoring), display, redisplay(retrieve), summarize, reports generation and **networking** of digital data collected by monitoring devices typically used to evaluate sleep and respiratory related sleep disorders. The device is to be used under the supervision of a physician. Use is restricted to files obtained from adult patients.

		physician. Use is restricted to files obtained from adult patients.		obstructive apneas (OSA), central sleep apneas (CSA), and hypopneas. Central sleep apneas (CSA) should be manually reviewed and modified as appropriate by a clinician. All events can be manually marked or edited within records during review. Photoplethysmography (PPG) total sleep time is not intended for use when electroencephalograph (EEG) data is recorded. PPG total sleep time is not intended to be used as the sole or primary basis for diagnosing any sleep related breathing	

				disorder, prescribing treatment, or determining whether additional diagnostic assessment is warranted.	
Intended Use	Same	Analyze physiological data previously recorded during sleep and present a report.	Analyze physiological data previously recorded during sleep and present a report.	Analyze pre-recorded physiological data acquired during sleep.	Analyze physiological data previously recorded during sleep and present a report.
Environment of Use	Same as Predicated Device	Healthcare Facility	Healthcare Facility	Physician office (data analysis and reporting). No limitation on where data are acquired.	Healthcare Facility
Input & Output Data (Result)					
Data format (Input)	Same as Predicated Device	EDF (European Data Format)	EDF (European Data Format)	EDF (European Data Format)	EDF (European Data Format)
Input Channel	Same (AASM Guidance)	EEG(F3, F4, M1, M2, C3, C4, O1, O2) EOG(E1, E2, M1, M2) Chin EMG ECG	EEG(F3, F4, M1, M2, C3, C4, O1, O2) EOG(E1, E2, M1, M2) Chin EMG ECG	EEG, ECG, EOG, EMG waveforms; SpO2; Respiratory effort; Airflow;	EEG EOG Chin EMG ECG Chest and abdomen

		Chest and abdomen movements measured by respiratory band Oxygen Saturation Respiratory Airflow Thermistor Leg EMG(Left/Right)	Chest and abdomen movements measured by respiratory band Oxygen Saturation Respiratory Airflow Thermistor Leg EMG(Left/Right)	Heart / pulse rate; Snoring loudness; Head movement and position.	movements measured by respiratory band Oxygen Saturation Respiratory Airflow Thermistor Audio Body Position Airway CO2 Leg EMG(Left/Right)
Output Result	Same as Predicated Device	Sleep Stage Arousal Apnea (Obstructive, Central, Mixed) / Hypopnea PLMs	Sleep Stage Arousal SBD (Sleep Breathing Disorder) PLMs	Sleep Stage Arousal Apnea (Obstructive, Central) / Hypopnea PLMs	Sleep Stage Arousal Apnea (Obstructive, Central, Mixed) / Hypopnea PLMs
Auto Scoring Algorithm					
Sleep Stage	Same	Five-stage Sleep Stage Scoring (Wake, Sleep Stage N1, N2, N3, REM)	Five-stage Sleep Stage Scoring (Wake, Sleep Stage N1, N2, N3, REM)	Five-stage Sleep Stage Scoring (Wake, Sleep Stage N1, N2, N3, REM)	Five-stage Sleep Stage Scoring (Wake, Sleep Stage N1, N2, N3, REM)
Arousal	Same as Predicated	Detects arousal event	Detects arousal event	Detects arousal event Respiratory-effort related	Detects arousal event

	device			arousal (RERA) Limb movement arousal Spontaneous cortical arousal	
Apnea	Same as Predicated device	Yes	Yes	Yes	Yes
Obstructive Apnea	Same as Reference device	Yes Detects OSA event	No. OSA must be manually scored	Yes Detects OSA event	Yes Detects OSA event
Central Apnea	Same as Reference device	Yes Detects CSA event	No. CSA must be manually scored	Yes Detects CSA event	Yes Detects CSA event
Mixed Apnea	Same as Predicated device	Yes Detects MSA event	No. MSA must be manually scored	No. MSA must be manually scored	Yes Detects MSA event
Hypopnea	Same	Yes	Yes	Yes	Yes
LM	Same	Yes	Yes	Yes	Yes
PLMs	Same	Yes	Yes	Yes	Yes
Manual Scoring (Edit)					
Event Edit (Add, Edit,	Same as Predicated	Yes Available Manual	Yes Available Manual Re-	No	No

Delete)	device	Scoring	Scoring		
Report					
AASM Polysomnography Report	Same	Yes	Yes	Yes	Yes
Customized Report	Same	Yes	Yes	Yes	No
Others					
Network	Same as Predicated device	No PC Stand-Alone	No PC Stand-Alone	Yes	Yes

7. Performance Data

7.1 Software Verification & Validation

The subject device software underwent verification and validation testing at the unit, integration, and system levels in accordance with FDA guidance and IEC 62304 processes. Testing was conducted on the final release version, and all test protocols were successfully executed with acceptable pass results. A regression analysis and regression testing were performed to ensure that modifications did not introduce unintended effects. Any anomalies identified during testing were resolved or determined, through risk assessment, not to impact safety or effectiveness. Collectively, the results demonstrate that the software performs as intended and supports substantial equivalence to the predicate device.

7.2 Clinical Study Summary of – U.S. STAGES Study

Study Design

An independent retrospective cross-sectional validation study was conducted to evaluate the clinical performance of SOMNUM (V.3.0.0) using 100 full-night PSG recordings selected from the National Sleep Research Resource (NSRR) STAGES dataset. PSG recordings were collected from four U.S. sleep centers: Bogan Sleep Consulting, Geisinger Health, MedSleep, and St. Luke's Hospital.

Reference Standard Generation

The reference standard was independently generated by three RPSGT-certified PSG technologists in accordance with AASM Scoring Manual criteria, without access to SOMNUM automatic scoring output. A 2/3 majority consensus approach was used to establish the final reference label for each epoch. Of 92,383 total epochs, 1,938 epochs (2.10%) were identified as non-consensus epochs and were independently adjudicated by a board-certified sleep physician serving as the final adjudicator. Reported performance metrics are based on consensus-scorable epochs and may not fully reflect device performance in the most clinically ambiguous cases. Non-consensus epochs occurred most frequently during N1 sleep stage classification (56.3% of non-consensus epochs), and device performance estimates may therefore be more optimistic in clinically ambiguous sleep stage classification cases than in routine clinical practice.

Patient Characteristics

The validation cohort included 100 adult subjects (50 male, 50 female). The mean age was 46.9 ± 14.17 years for male subjects and 49.1 ± 13.16 years for female subjects.

Performance Summary

1) **Test Data Utilized**

	Sex	Age	BMI
All	Male: 50	46.9(±14.17)	31.52(±7.56)
	Female: 50	49.1 (±13.16)	33.83(±8.27)

A total of 100 patient datasets were included, consisting of 50 males (mean age 46.9 years old) and 50 females (mean age 49.1 years old).
Race, Sex and BMI covered a wide range representing the characteristics typically observed in clinical practice.

Dataset included BMI values ranging from normal weight to overweight/obese, demonstrating that the algorithm's performance is not limited to a specific population subgroup. This dataset incorporated multi-center and multi-ethnic populations, supporting the generalizability of the software performance evaluation.

7.3 Test Result Summary

1) Data for End Point 1.

- Sleep Stage

Table 1 Performance Comparison of Sleep Stage

	SOMNUM					Reference				
	W	**N1**	**N2**	**N3**	**R**	**W**	**N1**	**N2**	**N3**	**R**
W	93.6% [93.3–93.9]	4.1% [3.8–4.3]	1.5% [1.3–1.6]	0.3% [0.2–0.4]	0.6% [0.5–0.7]	82.2	35.9	4.0	0.5	5.8
N1	4.3% [3.9–4.7]	81.4% [80.6–82.2]	12.4% [11.7–13.1]	0.4% [0.3–0.6]	1.5% [1.2–1.7]	9.6	26.1	4.7	0.4	8.7
N2	0.8% [0.8–0.9]	1.2% [1.1–1.3]	93.7% [93.5–94.0]	1.8% [1.7–2.0]	2.4% [2.3–2.6]	3.8	33.2	85.0	16.0	12.3
N3	1.9% [1.6–2.3]	0.7% [0.5–0.9]	6.7% [6.2–7.3]	87.9% [87.1–88.6]	2.8% [2.5–3.2]	0.2	0.2	5.4	82.3	0.0
R	4.3% [4.0–4.7]	0.7% [0.6–0.9]	4.2% [3.9–4.6]	0.9% [0.7–1.1]	89.8% [89.3–90.3]	4.2	4.7	0.8	0.8	73.2

- Arousal

Table 2. Performance Comparison of Arousal

SOMNUM			Reference [16]		
PPA	NPA	OPA	PPA	NPA	OPA
83.8% [82.62–84.97]	99.4% [99.35–99.45]	98.74 [98.67-98.82]	76.82	82.48	-

- Respiratory Event

Table 3. Performance Comparison of Respiratory Event

Respiratory Events	SOMNUM			Reference [17]		
	OPA	PPA	NPA	OPA	PPA	NPA
Hypopnea	98.58% [98.50–98.65]	81.71% [80.55–82.90]	99.29% [99.23–99.34]	95.5% [95.4- 95.6]	66.3% [64.9-67.6]	97.1% [97.0-97.2]
Obstructive Apnea	97.42% [97.31–97.51]	86.26% [85.58–86.99]	98.66% [98.58–98.73]	98.8% [98.7-98.8]	74.1% [72.1-76.1]	99.3% [99.2-99.3]
Central Apnea	99.83% [99.80–99.86]	82.19% [78.85–85.29]	99.93% [99.91–99.95]	98.9% [98.8- 99.0]	65.3% [63.1-67.6]	99.5% [99.5-99.0]
Mixed Apnea	99.94% [99.93–99.96]	75.67% [67.31–83.72]	99.97% [99.96–99.98]	-	76.3%	96.6%

- PLMs

Table 4. Performance Comparison of PLMS

SOMNUM			Reference [A10]		
OPA	PPA	NPA	OPA	PPA	NPA
97.63% [97.53 – 97.73]	87.18% [86.44–87.93]]	98.61% [98.53–98.69]	91.7% [91.5 - 91.8]	82.0% [81.0 - 83.0]	92.4% [92.2- 92.6]

- Conclusion

For Sleep Stage, Arousal, Respiratory Events and PLMS, SOMNUM exceeded all performance targets. “Compared with the clinical target of PPA, sleep staging showed an average improvement of 9.75% in concordance except for N1, while arousal and PLMS demonstrated performance improvements of 7%, and 5%, respectively. For respiratory event classification, SOMNUM demonstrated performance that was approximately 12–17% superior to the reference across all event categories except mixed sleep apnea (MSA).

For MSA classification, SOMNUM performance was within the confidence interval range

of the reference results, indicating comparable performance to the reference scoring.

-
- In conclusion, SOMNUM passed all pass/fail criteria for Endpoint 1.
-
- The number of epochs to calculate PPA/NPA for Endpoint1

2) Data for End Point 2.

Table 5. Performance Comparison of Relevant Scoring Variables Between SOMNUM and Performance Target for Endpoint 2.

Variable	Type Of Limit	SOMNUM	abs. MAX	Target	abs. MAX	Unit
TST	U	18	18	60	120	[min]
	L	-6		-120		
SE	U	2.5	2.5	10	13	%
	L	-1.5		-13		
SOL	U	8	8	40	40	[min]
	L	-8		-5		
ROL	U	6	6	170	170	[min]
	L	-5		-130		
Wake	U	6	18	60	60	[min]
	L	-18		-45		
N1	U	10	10	80	80	[min]
	L	-7		-60		
N2	U	10	10	70	120	[min]
	L	-8		-120		
N1_N2	U	15	15	70	70	[min]
	L	-8		-60		
N3	U	4.5	5	140	140	[min]
	L	-5		-10		
REM	U	8	8	50	80	[min]
	L	-6		-80		
Arousal Index	U	1.5	3			events/hour
	L	-3				

PLMS Index	U	4	15	7	43	events/hour
	L	-15		-43		
AHI Index	U	4	4	7	20	events/hour
	L	-3		-20		

- Conclusion

Bland-Altman and Deming regression analysis were performed to evaluate the relationship between SOMNUM-derived parameters and reference PSG measurements. The Bland-Altman analysis demonstrated generally consistent proportional relationships across the evaluated sleep and respiratory parameters without substantial systematic deviation. The Deming regression results demonstrated that all 13 evaluated variables satisfied the predefined linearity criteria.

3) Data for End Point 3.

Table 6. Likelihood ratio for AHI.

Sleep Apnea Diagnostic Agreement Clinical Performance Comparisons	**Per-Patient SOMNUM vs 2/3 Majority Sleep Apnea Diagnostic Agreement**				**Per-Patient K162627 vs 2/3 Majority Sleep Apnea Diagnostic Agreement**			
	Sleep		**REM**		**Sleep**		**REM**	
	AHI >= 5	AHI >= 15	AHI >= 5	AHI >= 15	AHI >= 5	AHI >= 15	AHI >= 5	AHI >= 15
Sample Size (N)	100	100	100	100	72	72	72	72
Sensitivity	100.0% (100.0-100.	98.28% (94.44-100.	100.0% (100.0-100.	95.45% (89.39-100.	91% (82%-98%)	95% (83%-100%)	83% (72%-94%)	79% (56%-94%)

	0)	0)	0)	0)				
Specificity	95.24% (83.33-100.0)	97.62% (92.10-100.0)	88.89% (71.43-100.0)	97.06% (90.32-100.0)	76% (61%-90%)	98% (94%-100%)	89% (79%-97%)	96% (90%-100%)
Accuracy	99.00% (97.00-100.0)	98.00% (95.00-100.0)	98.00% (95.00-100.0)	96.00% (92.00-99.00)	85% (77%-92%)	97% (93%-100%)	86% (79%-93%)	92% (85%-97%)
Likelihood ratio (+)	21.00	41.28	9.00	32.45	3.76	52.25	7.71	22.00
Likelihood ratio (-)	0.00	0.02	0.00	0.05	0.12	0.05	0.19	0.22

*** point estimates were calculated directly from the subject-level confusion matrix and 95% confidence intervals were estimated using subject-level bootstrap resampling with 1,000 iterations and the empirical percentile method.**

- Conclusion

  SOMNUM demonstrated high sensitivity and specificity across all evaluation conditions. In addition, LR+ values greater than 10 and LR− values below 0.1 were observed under most analysis conditions, suggesting that the device may provide clinically reliable diagnostic information for sleep apnea assessment. Notably, high sensitivity and low LR− values were maintained in REM sleep analyses, indicating relatively stable sleep apnea assessment performance under REM sleep conditions.

  Comparative analysis demonstrated that SOMNUM showed diagnostic performance generally comparable to or better than the predicate device (K162627) across multiple evaluation conditions. In particular, lower LR− values and consistently high sensitivity were observed under several analysis conditions, supporting reliable detection performance with a reduced likelihood of false-negative classification.

  Overall, these findings support that SOMNUM provides clinically reliable sleep apnea assessment performance across both Sleep and REM evaluation conditions.

7.4 Clinical Study Summary of Korean 48 case study

Korean 48 case study

Study Design

A retrospective cross-sectional clinical performance study was conducted to evaluate the performance of SOMNUM using 48 full-night polysomnography (PSG) recordings collected from three sleep laboratories. The validation dataset consisted of 48 PSG recordings selected from a total of 400 PSG studies. Device performance was evaluated by comparing SOMNUM automatic scoring results with an independently generated reference standard established using a 2/3 majority consensus of three qualified PSG technologists. Clinical performance was assessed using predefined statistical methods across three endpoints, including epoch-level agreement, subject-level agreement for sleep variables, and patient-level diagnostic performance for sleep apnea.\

Patient Characteristics

The study population consisted of 48 adult subjects, including 32 males and 16 females. The mean age was 44.2 ± 12.1 years (range: 21–67 years) for male subjects and 46.8 ± 16.6 years (range: 22–71 years) for female subjects. The mean body mass index (BMI) was 27.5 ± 3.3 kg/m² (range: 18.8–35.6 kg/m²) for male subjects and 25.5 ± 4.1 kg/m² (range: 18.8–35.6 kg/m²) for female subjects. The validation dataset consisted of 48 PSG recordings

Sample Size

A total of 48 full-night polysomnography (PSG) recordings were included in the clinical performance study. The validation dataset was selected from a total of 400 PSG recordings collected from three sleep laboratories and consisted of 24 Korean and 24 U.S. PSG recordings.

Institutional Source

PSG recordings were collected from three sleep laboratories in the Republic of Korea: Soonchunhyang University Hospital (Bucheon), Ajou University Hospital (Suwon), and Chungnam National University Hospital (Daejeon).

Performance Result

SOMNUM met all predefined acceptance criteria across the three clinical performance endpoints. For epoch-level analysis (Endpoint 1), the device demonstrated high agreement with the reference standard for sleep stage classification, arousal detection, respiratory event detection, and periodic limb movement (PLMS) detection, exceeding the predefined

performance targets. For subject-level analysis (Endpoint 2), all evaluated sleep variables demonstrated clinically acceptable agreement with the reference standard based on Bland–Altman analysis and Deming regression. For patient-level analysis (Endpoint 3), SOMNUM demonstrated excellent diagnostic performance for sleep apnea based on the apnea-hypopnea index (AHI), with likelihood ratios meeting or exceeding the predefined acceptance criteria. Overall, SOMNUM met or exceeded the performance of the predicate device across all evaluated endpoints.

8. Conclusion

Based on a comparison of the intended use and technological characteristics, performance test, the SOMNUM software is substantially equivalent to the identified predicate device. Minor differences in technological and performance characteristics did not raise new or different questions of safety and effectiveness. Bench testing and clinical performance testing demonstrated substantially equivalent performance to the predicate.