August 16, 2023

Honeynaps Co., Ltd
Tony Lee
Official Correspondent
4F, Marine Tech B/D, 529, Nonhyeon-ro, Gangnam-gu
Seoul, 06126
Korea, South

Re: K223922
Trade/Device Name: Somnum (v.1.1.2.)
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLZ
Dated: July 17, 2023
Received: July 17, 2023

Dear Tony 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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K223922

Device Name
SOMNUM

Indications for Use *(Describe)*
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, redisplay(retrieve), summarize and 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 adult patients.

For respiratory events - Sleep Disordered Breathing (Apneas and Hypopneas)- obstructive, central, mixed apneas, and hypopneas must be manually scored by physician. The device does not output specific apnea or hypopnea events and therefore should not be used for management decisions.

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.

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510(k) Summary

Device Name : SOMNUM (V.1.1.2. Final finished device)

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:
Date : September 30, 2022

Ⅰ. SUBMITTER

SUBMITTER :	Honeynaps 529, Nonhyeon-ro, Gangnam-gu Seoul, Republic of Korea 06126 Tel : +82-2-567-0134
CONTACT PERSON:	Honeynaps YoungJun Lee Chief Executive Officer tony.lee@honeynaps.com
PRIMARY CONTACT PERSON:	Honeynaps YoungJun Lee Chief Executive Officer tony.lee@honeynaps.com

Ⅱ. DEVICE

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 Polysomnograph with Electroencephalograph
Review Panel	Neurology

Ⅲ. PREDICATE DEVICE

510(k) Number	K162627
Applicant	ENSODATA
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 Polysomnograph with Electroencephalograph

510(k) Number	K112102
Applicant	YOUNES SLEEP TECHNOLOGIES
Device Name	MICHELE SLEEP SCORING SYSTEM
Regulation Number	21 CFR 868.2375
Regulation Name	Breathing Frequency Monitor
Regulation Class	II
Classification Product Code	MNR
Device Classification Name	Ventilatory Effort Recorder

Ⅳ. DEVICE DESCRIPTION

SOMNUM is a standalone software application that analyze previously recorded physiological data obtained during level 1 sleep studies, referred to as polysomnography (PSG) records. The SOMNUM software can analyze any EDF files. Automated algorithms are applied to the raw signals in order to identify the occurrence of certain events. The software automates recognition of:

- Sleep Stage Events : Wake, Stage N1, Stage N2, Stage N3, Stage REM
- Respiratory Events : Sleep Disordered Breathing (device output does not distinguish between Apneas and Hypopneas. Obstructive, central, mixed apneas, and hypopneas must be manually scored by physician)
- Arousal Events
- Leg Movement Events : Periodic Leg Movements during Sleep (PLMs)

The SOMNUM software can be used as a stand-alone application for use on Windows 10 operating system platform. All processing, scoring, and analysis of signal data occurs on local desktop PC.

Ⅴ. INDICATIONS FOR USE

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, 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.

For respiratory events - Sleep Disordered Breathing (Apneas and Hypopneas)- obstructive, central, mixed apneas, and hypopneas must be manually scored by physician. The device does not output specific apnea or hypopnea events and therefore should not be used for management decisions.

Table 1. Comparison of Indications for Use

Description	Subject Device SOMNUM	Predicate Device ENSOSLEEP (K162627)
Indications for Use	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, redisplay(retrieve), summarize, reports generation of digital data collected by monitoring devices typically used to evaluate sleep and respiratory related sleep disorders.	EnsoSleep is intended for use for the diagnostic evaluation by a physician to assess sleep quality and as an aid for the diagnosis of sleep and respiratory related sleep disorders in adults only. EnsoSleep is a software-only 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 obstructive apneas. All automatically

	The device is to be used under the supervision of a physician Use is restricted to files obtained from adults patients. For respiratory events - Sleep Disordered Breathing (Apneas and Hypopneas)- obstructive, central, mixed apneas, and hypopneas must be manually scored by physician. The device does not output specific apnea or hypopnea events and therefore should not be used for management decisions	scored events are subject to verification by a qualified clinician. Central apneas, mixed apneas, and hypopneas must be manually marked within records.
Intended Use	Analyze physiological data previously recorded during sleep and present a report.	Analyze physiological data previously recorded during sleep and present a report.
Environment of Use	Healthcare Facility	Healthcare Facility

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

There are no significant differences in the technological characteristics of this device compared to the predicate device which adversely affect safety or effectiveness. The below table is summarized and compared with the technological characteristics between the SOMNUM and the predicate device :

Table 2. Comparison of Technological Characteristics

Description	Subject Device SOMNUM	Predicate Device ENSOSLEEP (K162627)
Clinical Criteria :		
Clinical condition or purpose: Diagnosis of sleep and respiratory disorders	YES	YES
Population: Human subjects undergoing sleep studies	YES	YES
Five-stage Sleep Stage Scoring (Wake, REM, Three non-REM stages)	YES	YES
Arousal Scoring	YES	YES
Respiratory Events Scoring	YES	YES
Leg Movements Scoring	YES	YES
Performance assessed by percent agreement(and Cohen's kappa) between automatic and human scoring	YES	YES
Basic operation: processing of polysomnography data recorded from patients in sleep laboratories and polysomnography report generation	YES	YES
Data inputs for Sleep Stage and Arousal Scoring:		
Central electroencephalogram(EEG)	YES	YES
Left and right eye electrooccculogram(EOG)	YES	YES
Chin electromyogram(EMG)	YES	YES
Electrocardiogram (ECG)	YES	YES
Data inputs for Respiratory Events Scoring :		
Chest and abdomen movements measured by respiratory bands	YES	YES
Oxygen saturation	YES	YES

Respiratory airflow	YES	YES
Thermister	YES	YES
Audio	NO	YES
Body position	NO	YES
Airway CO2	NO	YES
Data inputs for Leg Movement Scoring :		
EMG recorded from right and left legs	YES	YES
Additional Technical Criteria :		
Polysomnography records scored per 30 second epoch	YES	YES
Cardiac artifacts removed from EEG, EMG and EOG channels	YES	YES
Others :		
Standard of scoring manual	The AASM Manual for the Scoring of Sleep and Associated Events, 2016	The AASM Manual for the Scoring of Sleep and Associated Events, 2007
Re-scoring	YES	YES
File Format	.EDF, .XML, .JSON format	.EDF, .
Network	Access to Internet is not required.	Access to Internet is required
Operating System	Windows 10	Windows XP, Windows 7, Windows 10

Ⅶ. PERFORMANCE DATA

Software Verification & Validation

Support for the substantial equivalence of the SOMNUM Software was provided as a result of risk management and software testing. Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guideline for Industry and FDA Staff, "Guidance for the Content of Premarket Submission for Software Contained in Medical Device."(Document issued on : May 11, 2005)

- Verification of each independent software subsystem against defined requirements
- Verification of interfaces between software subsystems against defined interface requirements
- Validation of fully integrated system including all subsystems against overall system requirements

The results of the verification and validation activities that have been performed demonstrate that the software meets requirements to support substantial equivalence.

Performance Test (Non-clinical test)

Performance testing was completed by evaluating SOMNUM device performance using a cross-sectional experimental design on a representative N=48 subjects of data recorded in the sleep laboratory. Substantial Equivalence was established through a testing protocol that used full night studies data to evaluate the performance of SOMNUM. The goal of the test reported here is to establish that SOMNUM performance is equivalent to the performance of the predicate device. We confirm that SOMNUM does not present any new concerns about safety or effectiveness compared to the predicate device, MICHELE Sleep Scoring System(K112102). The performance was measured by epoch by epoch agreement between SOMNUM's

automatic scoring and the scoring of three technologists using 2/3 majority rule, that is, at least two out of three export scoring(medical professionals certified on PSG recording and analysis) agree on the presenceof an event within an epoch. SOMNUM device performance was evaluated using the defined test design, statistical methodology, and controls across the following two endpoints:

Endpoint 1. As SOMNUM is intended to analyze physiological signals and automatically score sleep study results, including sleep staging and detection of respiratory events, arousal events, PLMs events, device performance for detecting each event type must be validated.

Endpoint 2. As SOMNUM is intended to present summary variables that appear in the clinical report used by physician to assess sleep disorders.

Test Result Summary

Data for End point 1

Sleep Stage

Table 3. Performance Comparison of sleep stage.

		SOMNUM					Reference[2]				
		W	N1	N2	N3	R	W	N1	N2	N3	R
Scorers	W	**89.96** (89.22-90.67)	6.93 (6.35-7.51)	0.86 (0.73-0.98)	0.14 (0.00-0.32)	4.13 (3.69-4.61)	**82.2**	35.9	4.0	0.5	5.8
	N1	6.15 (5.63-6.73)	**77.93** (76.95-78.86)	5.46 (5.16-5.78)	0.28 (0.09-0.52)	5.88 (5.38-6.43)	9.6	**26.1**	4.7	0.4	8.7
	N2	2.06 (1.75-2.41)	13.21 (12.42-13.96)	**91.13** (90.71-91.47)	15.52 (14.02-16.95)	5.37 (4.84-5.84)	3.8	33.2	**85.0**	16.0	12.3
	N3	0.01	0.07	1.84	**84.04**	0.00	0.2	0.2	5.4	**82.3**	0.0
	R	1.81 (1.49-2.14)	1.86 (1.53-2.19)	0.72 (0.60-0.84)	0.05 (0.00-0.14)	**84.62** (83.81-85.48)	4.2	4.7	0.8	0.8	**73.2**

Arousal

Table 4. Performance Comparison of sleep stage.

SOMNUM				Reference[3]			
Event Total Epoch	PPA	NPA	OPA	Event Total Epoch	PPA	NPA	OPA
13108	82.02 (81.42-82.64)	82.78 (82.41-83.17)	82.5 (82.2-82.9)	6468	76.82	82.48	-

SDB & PLMS

Table 5. Performance Comparison of sleep stage.

	SOMNUM				Reference[4]				Reference[1]			
	Event Total Epoch	PPA	NPA	OPA	Event Total Epoch	PPA	NPA	OPA	Event Total Epoch	PPA	NPA	OPA
SDB	15984	94.18 (93.79-94.52)	91.29 (90.98-91.61)	92.3 (92.1-92.6)	2439	75.5	98.1	93.0	4705	67 (58, 75)	93 (92, 94)	91 (90, 92)
PLMS	5215	92.89 (92.18-93.55)	94.30 (94.08-94.51)	94.1 (93.9-94.4)	1741	78.4	97.6	95.7	5796	71 (60, 80)	90 (89, 92)	89 (87, 90)

Please note that Event total Epoch means the total number of epochs with events. The total epoch is 43971 epochs (event epoch + non-event epoch).

Discussion:

For Sleep Stage and Arousal, SOMNUM exceeded all performance targets, while for SDB and PLMS, SOMNUM exceeded the performance targets for PPA. Comparing NPA of PLMS of SOMNUM with that of predicate device, the NPA of SOMNUM' is 3.3% lower. however, it is unknown whether a statistically significant comparison can be made due to lack of CI. Therefore, the NPA of K162627 was compared as the reference device, and in this case, SOMNUM showed good performance by 4.3%. In conclusion, the NPA performance for PLMS is considered to be within clinically acceptable range. The NPA for SDB showed a performance that was 1.7% lower than K162627 and about 6.8% lower than K112102. However, considering both PPA and OPA of SOMNUM, the overall performance of SOMNUM is better than that of K162627. In addition, considering the situation where there is no standard reference, it cannot be said that this difference shows the low performance of SOMNUM. Furthermore, the manual scorer agreement[8], which is generally acceptable in clinical practice, is considered to have an error range of around 15%, these performance differences are considered to be within the clinically acceptable error range.

In conclusion, SOMNUM passed all pass/fail criteria for Endpoint 1.

Data for End point 2:

Table 6. 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	10	20	60	120	[min]
	L	-20		-120		

SE	U	2.5	5	10	13	%
	L	-5		-13		
SOL	U	8	23	40	40	[min]
	L	-23		-5		
ROL	U	120	120	170	170	[min]
	L	-70		-130		
Wake	U	22	22	60	60	[min]
	L	-10		-45		
N1	U	30	45	80	80	[min]
	L	-45		-60		
N2	U	65	65	70	120	[min]
	L	-50		-120		
N1_N2	U	55	55	70	70	[min]
	L	-35		-60		
N3	U	30	40	140	140	[min]
	L	-40		-10		
REM	U	20	40	50	80	[min]
	L	-40		-80		
Arousal Index	U	30	30	-	-	events/hour
	L	-20		-		
PLMS Index	U	43	43	7	43	events/hour
	L	-2		-43		
AHI Index	U	18	18	7	20	events/hour
	L	-7		-20		

Discussion: TST, SE, ROL, Wake, N1, N2, N1_N2, and REM satisfy the provided Upper and Lower LOA.

However, SOL has a target of -5 to 40, while SOMNUM has a range of -23 to 8, and N3 has a target of -10 to 140, while SOMNUM has a range of -40 to 30. The PLMS index has a target of -40 to 10, but SOMNUM has a range of -2 to 43, and the AHI index has a target of -20 to 7, but SOMNUM has a range of -7 to 18.

When considering the actual range of absolute errors, SOL has a target of 40 minutes, while SOMNUM has 23 minutes, and N3 has a target of 140, while SOMNUM has 40 minutes. The AHI index has a target of 22, but SOMNUM has 18, resulting in smaller absolute errors.
PLMS index has a target of 43, while SOMNUM has 43, it shows the almost same value. However, considering the 15% error among scorers presented in Reference [8], it cannot be said that it affects the performance.

In addition, we compared the LOA of Relevant Sleep Scoring Variables of SOMNUM and those of References. The table 12 showed the LOA of SOMNUM and References.

Table 7. Performance Comparison of LOA between SOMNUM and References for Endpoint 2

Variable	LOA	SOMNUM	References	Ref. No.	Unit
TST (Total Sleep Time)	U	7.8	35	[5]	[min]
	L	-14.21	-70		
SE (Sleep Efficiency)	U	1.69	10	[7]	%
	L	-3.31	-12		
SOL (Sleep On Latency)	U	2.93	15	[7]	[min]
	L	-4.21	-11		
ROL (REM On Latency)	U	62.01	70	[5]	[min]
	L	-60.69	-90		
Wake	U	14.21	70	[7]	[min]
	L	-7.80	-45		
N1	U	25.30	30	[5]	[min]
	L	-17.29	-30		
N2	U	31.61	10	[5]	[min]
	L	-29.10	-75		
N1_N2	U	31.58	30	[5]	[min]
	L	-19.17	-75		
N3	U	18.83	65	[5]	[min]
	L	-30.45	-5		
REM	U	6.07	18	[5]	[min]
	L	-31.95	-55		
Arousal Index	U	23.91	-	-	events/hour
	L	-15.21	-		
PLMS Index (Periodic Limb Movements of Sleep Index)	U	12.24	13	[6]	events/hour
	L	-0.37	-15		
AHI Index (Apnea-Hypopnea Index)	U	8.79	4	[5]	events/hour
	L	-3.28	-2		

When comparing the LOA ranges of SOMNUM and References, the CI ranges of SOMNUM is narrower than those of the references except for AHI. In conclusion, SOMNUM passed all pass/fail criteria for Endpoint 2.

Output Comparison Data

SCORING FUNCTION	SOMNUM					ENSOSLEEP(K162627)				
	Total Epochs	PPA (%)	NPA (%)	OPA (%)	kappa (%)	Total Epochs	PPA (%)	NPA (%)	OPA (%)	kappa (%)
SLEEP STAGING	43971			87.5 (87.2,87.8)	82.1 (81.6,82.5)	59719	78 (77,80)	95 (94,95)	91 (91,92)	
Awake	6719	89.9 (89.2,90.6)	97.4 (97.3,97.6)			17459	86 (82,88)	97 (95,98)	94 (92,95)	
N1	6522	77.9 (77.0,78.9)	94.6 (94.4,94.9)			3293	41 (33,48)	94 (93, 96)	91 (90,93)	
N2	20448	91.1 (90.7,91.5)	92.4 (92.0,92.7)			26839	77 (73,81)	87 (85,90)	83 (80,85)	
N3	1012	84.1 (82.6,85.6)	99.1 (99.0,99.2)			5587	81 (74,88)	93 (91,95)	92 (90,94)	
REM	7364	84.7 (83.8,85.4)	98.9 (98.8,99.0)			6541	79 (72,84)	99 (98,99)	96 (96,97)	
No Consensus	756					1432				
AROUSAL	43971			82.5 (82.2,82.9)	60.8 (60.1,61.5)	59719			87 (85,88)	-
Yes	13108	82 (81.4,82.6)	82.8 (82.4,83.2)			7686	66 (61,71)	90 (88,91)		
None	30863									
No Consensus	0					0				
PLMS	43971			94.1 (93.9,94.4)	75.7 (74.7,76.5)	59719			89 (87,90)	-
Yes	8509	92.9 (92.1,93.6)	94.3 (94.1,94.5)			5796	71 (60,80)	90 (89,92)		
None	35462									
No Consensus	0									
RESPIRATORY EVENTS	43971			92.3 (92.1,92.6)	83.8 (83.2,84.3)	59719			91 (90,92)	-
YES	15984	94.2 (93.8,94.5)	91.3 (91.0,91.6)			4705	67 (58,75)	93 (92,94)		
None	27987									
No Consensus	0					0				

Discussion : Except for the NPA of Arousal, SOMNUM is superior to the predicate device in all PPA and NPA. However, the NPA of arousal is about 8% lower, but this is within the limit that can be seen between general scorers. The manual scorer agreement[8], which is generally acceptable in clinical practice, is considered to have an error range of around 15%, these performance differences are considered to be within the clinically acceptable error range.

Clinical Test Summary

No clinical studies were considered necessary and performed.

Summary

In summary, performance test results demonstrated that SOMNUM achieved sleep staging, sleep disordered breathing, arousal, PLMs events detection agreement that is substantially equivalent to the predicate device Ensosleep (K162627) and MICHELE Sleep Scoring(K112102) performance for all comparisons in all endpoints analyzed respectively. The SOMNUM performance validation testing demonstrates the safety and effectiveness of SOMNUM whenused for the defined indications for use. The performance data demonstrates that the SOMNUM device performs comparably to the predicate device that is currently marketed for the same intended use.

References

[1] FDA, 510(k) Summary(MICHELE Sleep Scoring System, K112102)

[2] DJ Levendowski, et. al, "The Accuracy, Night-to-Night Variability, and Stability of Frontopolar Sleep Electroencephalography Biomarkers" Journal of Clinical Sleep Medicine, Vol. 13, No. 6, pp.791 – 803, 2017

[3] F De Carli, et. al, "A Method for the Automatic Detection of Arousals During Sleep" Sleep, Vol. 22, No. 5, pp. 561~572, 1999

[4] FDA, K162627 510K summary report

[5] Atul Malhotra, et. al., "Performance of an Automated Polysomnography Scoring System Versus Computer-Assisted Manual Scoring" SLEEP, Vol. 36, No. 4, pp. 573-582, 2013

[6] S. D. Pittman, et. al., "Assessment of Automated Scoring of Polysomnographic Recordings in a Population with Suspected Sleep-disordered Breathing", SLEEP, Vol. 27, No. 7, 2004 pp.1394-1403

[7] C. Stepnowsky, et. al, "Scoring accuracy of automated sleep staging from a bipolar electroocular recording compared to manual scoring by multiple raters, Sleep Medicine 14 (2013) 1199–1207

[8] T. Penzel, "Sleep scoring moving from visual scoring towards automated scoring", *SLEEP*, 2022, Vol. 45, No. 10. pp. 1 – 3.

Ⅶ. CONCLUSIONS

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. Additionally, the non-clinical testing supports that the system performs in accordance with its intended use and is as safe, as effective, and performs as well as the predicate device.