June 18, 2025

Happy Health Inc.
℅ Rakesh Lal
Consultant
Rx Device Consulting
7 Courtyard Pl
Lexington, Massachusetts 02420

Re: K242224
Trade/Device Name: Happy Health Home Sleep Test
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing frequency monitor
Regulatory Class: Class II
Product Code: MNR
Dated: July 29, 2024
Received: July 29, 2024

Dear Rakesh Lal:

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,
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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.

510(k) Number *(if known)*
K242224

Device Name
Happy Health Home Sleep Test

Indications for Use *(Describe)*

The Happy Health Home Sleep Test is a Software as a Medical Device that uses data from wearable devices to record, analyze, display, export, and store biophysical parameters to aid in evaluating sleep-related breathing disorders of adult patients suspected of sleep apnea. The device is intended for use on individuals who are 22 years of age or older in clinical and home settings under the direction of a trained healthcare provider.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

This 510(k) summary is submitted in accordance with the requirements of 21 CFR 807.92

CONTACT DETAILS

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PROPOSED DEVICE

Device Trade Name:	Happy Health Home Sleep Test
Common Name:	Breathing frequency monitor
Classification Name:	Ventilatory Effort Recorder
Regulation Number:	868.2375
Product Code(s):	MNR

PREDICATE DEVICE

Primary Predicate

Device Name:	NightOwl (K191031)
Classification Name:	Ventilatory Effort Recorder
Regulation Number:	868.2375
Product Code:	MNR

Reference Device

Device Name:	Belun Sleep System BLS-100 (K222579)
Classification Name:	Ventilatory Effort Recorder
Regulation Number:	868.2375
Product Code:	MNR

DEVICE DESCRIPTION

The Happy Health Home Sleep Test is a Software as a Medical Device that uses data from wearable devices to record, analyze, display, export, and store biophysical parameters to aid in evaluating sleep-related breathing disorders of adult patients suspected of sleep apnea.

The device is intended for use on individuals who are 22 years of age or older in clinical and home settings under the direction of a trained healthcare provider. The device is intended to process input data streams received from an external hardware device (i.e., a smart ring, K240236) and uses these signals to determine various sleep parameters that may be used and interpreted by a clinician in diagnosing sleep disorders such as sleep apnea.

The input physiologic signals from the external device are:

- Acceleration / Movement
- Photoplethysmography (PPG)

The external hardware device (K240236) includes a PPG sensor and accelerometer embedded within a housing to capture the above physiological signals. The K240236 device is worn on the finger and is indicated for continuous data collection of the above signals. Data from the external hardware device is transmitted over a secure API to the subject device for analysis.

The device then uses a set of algorithms to compute the following outputs:

- Happy Health Apnea Hypopnea Index (hAHI)
- Total Sleep Time

The outputs are available for a clinician to review as a report, accessible through a web-based viewer application.

INTENDED USE / INDICATIONS FOR USE

The Happy Health Home Sleep Test is a Software as a Medical Device that uses data from wearable devices to record, analyze, display, export, and store biophysical parameters to aid in evaluating sleep-related breathing disorders of adult patients suspected of sleep apnea. The device is intended for use on individuals who are 22 years of age or older in clinical and home settings under the direction of a trained healthcare provider.

COMPARISON WITH PREDICATE DEVICE & REFERENCE DEVICE

The table below further summarizes the comparison in intended use and technological characteristics.

Characteristic	Subject Device	Predicate Device (K191031)	Reference Device (K222579)	Comparison
	Happy Health Home Sleep Test	**NightOwl**	**Belun Sleep System BLS-100**	
Regulation	21 CFR 868.2375	23 CFR 868.2375	22 CFR 868.2375	**Equivalent**
Class	II	II	II	**Equivalent**
Product Code	MNR – Ventilatory Effort Recorder	MNR – Ventilatory Effort Recorder	MNR – Ventilatory Effort Recorder	**Equivalent**

Indications for Use	The Happy Health Home Sleep Test is a Software as a Medical Device that uses data from wearable devices to record, analyze, display, export, and store biophysical parameters to aid in evaluating sleep-related breathing disorders of adult patients suspected of sleep apnea. The device is intended for use on individuals who are 22 years of age or older in clinical and home settings under the direction of a trained healthcare provider.	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).	**Equivalent** - the subject device and predicate device both have very similar indications for use. All three devices have the same intended use as an aid in evaluating sleep disorders in adults.
Use Environment	Home and clinical settings	Home and clinical settings	Home and clinical settings	**Equivalent**

Target population	Adults (22+) suspected of having sleep disorders	Adults (22+) suspected of having sleep disorders	Adults (22+) suspected of having sleep disorders	**Equivalent**
Hardware	SaMD device, compatible with K240236 (smart ring device worn on the finger) that uses an optical plethymosgraphy sensor and an accelerometer sensor	Wearable device worn on the fingertip for data capture. Uses optical plethysmography sensor and accelerometer.	Wearable device, worn on the proximal phalanx of the index finger	**Equivalent** - the subject device is a SaMD product that is intended to work with compatible hardware devices, while the predicate and reference include hardware. The compatible hardware devices that work with the subject device meet the same requirements as the predicate and reference devices. This difference does not raise new questions of safety and effectiveness.
Software	Yes, compliant with IEC 62304	Yes, compliant with IEC 62304	Yes, compliant with IEC 62304	**Equivalent**

Input Channels	Actigraphy, PPG	PAT, Pulse rate, Oximetry and Actigraphy channels	PPG, Pulse rate, Oximetry, Actigraphy	**Equivalent** - all devices use similar input channels, though minor differences in specific channels exist. The differences do not raise new questions of safety and effectiveness.
Algorithm Outputs	hAHI, Total sleep time	pAHI, Total sleep time	bAHI, bSTAGES, bTST	**Equivalent** - the subject device and predicate device both include AHI and TST outputs, as does the reference device. Differences do not raise new questions of safety and effectiveness.

AHI Algorithm	Outputs PAT derived Happy Health AHI (hAHI)	Outputs PAT derived AHI (pAHI)	bAHI calculation tuned to the AASM's '1B Rule' for the scoring of hypopnea	**Equivalent** - all devices report an AHI score based on AASM. The specific method of computing AHI is different across the devices. The subject device and predicate device both use peripheral arterial tone (PAT) to compute the AHI value. Differences in specific implementation of the AHI algorithms do not raise new questions of safety and effectiveness. Clinical validation demonstrates that the hAHI is comparable to human manual scoring of AHI with an accuracy similar to the predicate and reference devices.

AHI Performance	Regression: PSG_AHI = 0.98 * hAHI + 0.81 Bland Altman Limits of Agreement: -9.8 to 10.7 events/hr	Regression: AHI (Expert PSG) = 0.9981 * pAHI (NightOwl) + 2.235 Sensitivity (cutoff of 5): 0.943 and 0.936 Specificity (cutoff of 5): 0.813 and 0.727 (Sensitivity and specificity were evaluated in two trials)	Sensitivity (cutoff of 15 and 30): 0.898 and 0.849 Specificity (cutoff of 15 and 30): 0.860 and 0.951 Accuracy (cutoff of 15 and 30): 0.877 and 0.925	**Equivalent** - both subject and predicate devices demonstrate strong correlation with manually scored AHI, each with a regression slope between 0.9 and 1.1 and intercept between -5 and 5.
Sleep Algorithm	Outputs total sleep time (TST)	Outputs total sleep time (TST)	Outputs Wake, REM and NREM and total sleep time (TST)	**Equivalent** - the subject and predicate device both report total sleep time, as does the reference. The minor differences do not raise new questions of safety and effectiveness. Clinical validation demonstrates that the subject device's TST is comparable to human manual scoring of TST with an accuracy similar

				to the predicate and reference devices.
TST Performance	The mean absolute difference between subject device's TST and expert labeled TST was 24.9 minutes with a standard deviation of 32.6 minutes	Not provided	The mean absolute difference between bTST and PSG-TST was 30.8 minutes with a standard deviation of 41.6 minutes	**Equivalent** - both subject and reference devices demonstrate strong correlation with manually scored AHI, each with a mean absolute difference of around 30 minutes or less.

PERFORMANCE TESTING

Non-Clinical Testing Summary

Non-clinical testing of the Happy Health Home Sleep Test included:

- Software V&V testing in accordance with FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices and with IEC 62304

- Cybersecurity in accordance with FDA Guidance Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions

- Usability testing in accordance with FDA Guidance for Applying Human Factors and Usability Engineering to Medical Devices

Clinical Testing Summary

A clinical study was performed to evaluate the performance of the hAHI compared to polysomnography performed at two sleep labs. Data from a total of 90 subjects referred to the sleep clinic by a physician was manually scored in accordance with the American Academy of Sleep Medicine (AASM) guidelines to determine apnea and hypopnea events. The Happy Apnea Hypopnea Index (hAHI) was compared to the counts of the manually scored apnea and hypopnea events. Analysis of the data shows that hAHI correlates well with the PSG AHI. A regression analysis revealed a Deming regression with an R value of 0.98 and the equation: PSG_AHI = 0.98 * hAHI + 0.81. The table below provides the results of Deming regression analysis and Bland Altman analysis.

Analysis	Parameter	Value [95% CI]
Regression Analysis	Slope	0.98 [0.91, 1.06]
	Intercept	0.81 [-0.35, 1.91]
Bland Altman Analysis	Mean bias	0.5 [-0.1,1.1]
	Lower LOA	-9.8 [-10.6, -9]
	Upper LOA	10.7 [-9.9, 11.5]

Additional clinical validation was performed to assess the total sleep time of the Happy Health Home Sleep Test. Data from the same 90 subjects was analyzed and compared to manually labeled polysomnography data. The mean absolute difference between total sleep time measured by the Happy Health Home Sleep Test and manually labeled PSG data was 24.9 minutes with a standard deviation of 32.6 minutes.

CONCLUSION

Based on the results of the nonclinical and clinical testing, the Happy Health Home Sleep Test is substantially equivalent to the predicate device.