August 5, 2024

Big Health, Inc.
Reuben Lawson
Vice President, Regulatory Affairs & Quality Systems
461 Bush St.
Suite 200
San Francisco, California 94108

Re: K233577
Trade/Device Name: Sleepio®
Regulation Number: 21 CFR 882.5801
Regulation Name: Computerized Behavioral Therapy Device For Psychiatric Disorders
Regulatory Class: Class II
Product Code: QVO
Dated: June 24, 2024
Received: June 24, 2024

Dear Reuben Lawson:

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.

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,

Robert Kang -S

for Pamela Scott
Assistant Director
DHT5B: Division of Neuromodulation and Rehabilitation 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233577

Device Name
Sleepio

Indications for Use *(Describe)*
Sleepio is a digital therapeutic intended for the treatment of chronic insomnia / insomnia disorder as an adjunct to usual care in patients aged 18 and older. Sleepio is a prescription device delivering Cognitive Behavioral Therapy for Insomnia (CBT-I) and can be made available on the order of a licensed 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 - K233577

1. Submitter

Submitted by:	Big Health Inc.
Contact Name:	Reuben Lawson, Vice President, Quality Systems & Regulatory Affairs
Contact Phone:	(949) 439 3629
Additional Contact:	Dr. Alasdair L. Henry, Senior Manager, Clinical Research

2. Device

Device name:	Sleepio
Classification name:	Computerized Behavioral Therapy for Psychiatry Disorders (21 CFR 882.5801)
Regulatory class:	Class II (Special Controls)
Product code:	QVO

3. Predicate device

Device name:	Somryst
Manufacturer:	Pear Therapeutics
Classification name:	Computerized Behavioral Therapy for Psychiatry Disorders (21 CFR 882.5801)
Regulatory class:	Class II (Special Controls)
510(k) Number:	K191716
Product code:	QVO

4. Device Description

Sleepio is a digital therapeutic for the treatment of chronic insomnia / insomnia disorder. Sleepio treats chronic insomnia / insomnia disorder by delivering evidence-based techniques targeting the cognitive and behavioral factors that maintain insomnia and chronic sleep problems. Patient experience is tailored based on symptoms and daily sleep tracking. In addition to core therapeutic components, there is in-the-moment therapeutic content for help falling asleep. Content is delivered via smartphone and tablet applications (iOS and Android), as well as via web. Sleepio is intended as an adjunct to usual care treatment for chronic insomnia / insomnia disorder by a healthcare provider. Healthcare providers have access to a dashboard to track patient engagement with Sleepio.

5. Intended use / Indications for use

Sleepio is a digital therapeutic intended for the treatment of chronic insomnia / insomnia disorder as an adjunct to usual care in patients aged 18 and older. Sleepio is a prescription device delivering Cognitive Behavioral Therapy for Insomnia (CBT-I) and can be made available on the order of a licensed healthcare provider.

6. Substantial equivalence

Sleepio has an identical intended use and nearly identical technological characteristics compared to the predicate device, Somryst. Like Somryst, Sleepio delivers cognitive behavioral therapy for insomnia (CBT-I) by way of an app provided as an adjunct to usual care by the patient's healthcare provider. However, Sleepio is available for use in patients aged 18 and older, whereas Somryst is available for use in patients aged 22 and older. Patients can only access the product on the order of a licensed healthcare provider, who will themselves have access to patient progress through an online portal where salient patient information is provided.

Table 1: Substantial Equivalence of Technological Characteristics

Category	Sleepio (this submission)	Somryst (predicate)
510(k) number	K233577	K191716
Classification regulation	21 CFR 882.5801 Computerized behavioral therapy device for psychiatric disorders	21 CFR 882.5801 Computerized behavioral therapy device for psychiatric disorders
Intended use	SaMD intended to be computerized behavioral therapy device to treat patients with chronic insomnia / insomnia disorder	SaMD intended to be computerized behavioral therapy device to treat patients with chronic insomnia
Indications for use	Sleepio is a digital therapeutic intended for the treatment of chronic insomnia / insomnia disorder as an adjunct to usual care in patients aged 18 years and older. Sleepio is a prescription device delivering Cognitive Behavioral Therapy for Insomnia (CBT-I) and can be made available on the order of a licensed healthcare provider.	Somryst is a prescription-only digital therapeutic intended to provide a neurobehavioral intervention (Cognitive Behavioral Therapy for Insomnia - CBT-I) in patients 22 years of age and older with chronic insomnia. Somryst treats chronic insomnia by improving a patient's insomnia symptoms
Mechanism of action	Consolidation and regularization of sleep-wake cycle, restructuring dysfunctional beliefs and attitudes about sleep, cognitive-behavioral reconditioning, reducing sleep-related anxiety and arousal	Consolidation and regularization of sleep-wake cycle, restructuring dysfunctional beliefs and attitudes about sleep, cognitive-behavioral reconditioning, reducing sleep-related anxiety and arousal
Medical Device Type	Software as a Medical Device (SaMD)	Software as a Medical Device (SaMD)

Access	Prescription only	Prescription only
Adjunct use	Adjunct to supervised outpatient treatment	Adjunct to supervised outpatient treatment
Mobile platform	Mobile application (Smartphones, tablets [iOS and Android]), and web application	Mobile application (Smartphones, tablets [iOS and Android])
Software architecture	Patient facing mobile application or website, clinician facing dashboard, backend services	Patient facing mobile application, clinician facing dashboard, backend services

7. Performance data

7.1. Summary of nonclinical performance data

Software verification and validation testing was completed and documentation was provided as recommended by Guidance for Industry and FDA Staff: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (2005), for a Moderate level of concern device.

7.2. Summary of clinical performance data

Sleepio was evaluated in the Clinical Effectiveness of Digital Insomnia Therapy (CrEDIT) trial which was a two-arm, parallel group, randomized controlled trial (RCT) comparing digital CBT (Sleepio) with online sleep hygiene education in 336 adults aged 22+ with insomnia disorder, as diagnosed in the DSM-5. Participants were recruited from across the United States via social media. Participants were allocated to receive Sleepio (n=168) or online sleep hygiene education (SHE; n=168) in addition to their usual care.

The co-primary endpoints were insomnia severity, assessed using the insomnia severity index (ISI), sleep diary sleep onset latency (SOL) and wake after sleep onset (WASO) at 10 weeks post-randomization. Analyses were performed to evaluate the odds of insomnia response (reduction in ISI score of ≥8) and remission (ISI<8) at 10 weeks. Follow-up assessments occurred at 16 and 24 weeks post- randomization. Secondary outcomes included insomnia symptoms assessed by the Sleep Condition Indicator (SCI-8).

The average age of the sample was 46.4 (SD=9.9) years. The study sample closely mapped onto the US population on racial and socioeconomic characteristics. See Table 2 for a summary of the study demographics and comparison with the US population.

Table 2: Summary of the CrEDIT trial study demographics and comparison with the US population.

Demographic characteristics	Sleepio pivotal trial (CrEDIT)	Comparison to US population
Gender, Female, %	56%	50.2%[1]
Race, White, %	71%	59%[2]
Education, College degree or higher, %	56%	54%[3]
Income	61% with income ≤$74,999	Median = $74,580[4]
Employment, Full time, %	48%	52%[5]

Study Results

A summary of the ITT sample results of the CrEDIT trial for Sleepio vs SHE is provided in Tables 3 and 4 below. A subsequent post-hoc analysis was conducted in participants who had ≤6.5 hours sleep duration at baseline and results for this subgroup are presented in Table 5. Note the data in table 4 was calculated post-hoc because LS Mean difference was not the statistical analysis method originally pre-specified in the statistical analysis plan.

Table 3: ISI, SOL and WASO summary statistics by group and time, and estimated treatment effects at week 10 (primary outcome), and week 16 (follow-up) and week 24 (long-term follow-up). Effects are between-group mean differences.

Assessment	Unadjusted mean (SD); n		Adjusted difference (SE)	99% CI	*p*-value	Cohen's *d*
	SHE	Sleepio				
ISI						
Baseline	18.33 (4.19); 168	18.12 (3.72); 168				

[1] US Census Bureau (2023). https://www.census.gov/content/dam/Census/newsroom/press-kits/2023/paa/2023-paa-paper-financial-insecurity-hardship-pulse-gender-identity-sex.pdf

[2] US Census Bureau (2020). https://www.census.gov/quickfacts/fact/table/US/PST045222

[3] Lumina Foundation. (2023). https://www.luminafoundation.org/stronger-nation/report/#/progress

[4] US Census Bureau (2022). Income in the United States: 2022. https://www.census.gov/library/publications/2023/demo/p60-279.html

[5] Bureau of Labor Statistics (2022). Work Experience of the Population. https://www.bls.gov/news.release/pdf/work.pdf

Week 10	14.74 (5.00); 156	12.11 (6.10); 138	-2.37 (0.56)	-3.81, -0.92	<0.001	0.60[6]
Week 16	14.60 (5.19); 153	11.37 (5.67); 129	-2.55 (0.57)	-4.01, -1.09	<0.001	0.65
Week 24	14.80 (5.49); 147	11.00 (5.93); 125	-3.05 (0.59)	-4.56, -1.54		0.77
SOL						
Baseline	53.92 (41.83); 168	54.30 (38.41); 168				
Week 10	45.54 (48.82); 157	36.75 (32.00); 132	-9.14 (3.63)	-18.49, 0.20	0.012	0.23
Week 16	38.82 (38.23); 153	32.56 (29.70); 124	-6.68 (3.69)	-16.18, 2.83	0.070	0.17
Week 24	36.49 (40.73); 147	32.80 (43.59); 122	-4.37 (3.99)	-14.64, 5.90		0.11
WASO						
Baseline	46.06 (31.45); 168	48.71 (50.71); 168				
Week 10	33.82 (30.06); 157	24.54 (21.40); 132	-8.86 (2.94)	-16.42, -1.29	0.003	0.21
Week 16	35.27 (32.75); 153	23.97 (23.32); 124	-11.69 (2.97)	-19.35, -4.03	<0.001	0.28
Week 24	35.64 (35.10); 147	24.11 (27.03); 122	-12.02 (3.19)	-20.24, -3.80		0.29

[6] Effect size when calculated using the standard deviation of ISI change at week 10, the effect size is d=0.47

Table 4: LS mean differences for Sleepio and SHE at post-intervention and 24 week follow-up in the ITT sample

		Sleepio pivotal trial (CrEDIT) ITT analysis		
Assessment	**Timepoint**	**Sleepio LS Mean**	**SHE LS Mean**	**Sleepio LS Mean difference (95% CI)**
ISI	Post-treatment	-6.03	-3.66	-2.37 (-3.53, -1.21)
	24-week follow-up	-6.82	-3.86	-2.97 (-4.30, -1.63)
SOL	Post-treatment	-17.50	-8.05	-9.45 (-17.90, -1.01)
	24-week follow-up	-22.49	-16.68	-5.81 (-15.96, 4.34)
WASO	Post-treatment	-21.70	-11.43	-10.26 (-19.02, -1.49)
	24-week follow-up	-20.45	-10.13	-10.32 (-20.10, -0.56)

Table 4 note: The reported 95% CIs for week 24 follow-up are not from pre-specified hypothesis tests and are without multiplicity adjustment.

Table 5: LS mean differences for Sleepio and SHE at post-intervention and 24 week follow-up in participants with ≤6.5 hours sleep duration at baseline

		Sleepio pivotal trial (CrEDIT) with ≤6.5 hours sleep duration		
Assessment	**Timepoint**	**Sleepio LS Mean**	**SHE LS Mean**	**Sleepio LS Mean difference (95% CI)**
ISI	Post-treatment	-6.44	-3.98	-2.46 (-4.42,-0.50)
	24 week follow-up	-7.43	-3.65	-3.77 (-6.06, -1.48)
SOL	Post-treatment	-18.25	-2.39	-15.85 (-32.39, 0.69)
	24 week follow-up	-29.24	-16.87	-12.37 (-26.93, 2.18)
WASO	Post-treatment	-33.79	-10.69	-23.10 (-42.37, -3.84)
	24 week follow-up	-33.67	-7.76	-25.91 (-46.70, -5.11)

Table 5 note: The reported 95% CIs are not from pre-specified hypothesis tests and are without multiplicity adjustment.

Remission and Responder Analyses

Treatment response and remission were assessed using the ISI. In pre-specified analyses, response was defined as a change of ≥6 points from baseline, and remission defined as a score of <8. At 10 weeks, Sleepio participants had 2.52 odds of response (OR=2.52; p<0.001, 99% CI: (1.33, 4.75)), and 5.8 odds of remission (OR=5.78; p<0.001, 99% CI: (2.11, 15.84)) compared with SHE. A post-hoc response analysis using a definition of a change of ≥8 points from baseline on the ISI showed that Sleepio participants had 3.30 odds ratio of response compared to SHE participants (OR=3.30; 95% CI: (1.92, 5.69)).

Note: Odds ratio >1 for ISI means the odds of being in remission/response are higher in Sleepio than Control Group.

No adverse or serious adverse events were reported by participants.

8. Conclusion

Sleepio and the predicate Somryst have the same Intended Use as computerized behavioral therapy devices for psychiatric disorders. There are slight differences in indications for use in that Sleepio is considered appropriate for transitional adolescents (18-21) as well as adults (22+) but this does not constitute a new intended use. Sleepio has similar technological characteristics to Somryst, including software architecture, delivery of digital behavioral therapy through a mobile application, and therapeutic content. Software testing and pivotal clinical study results validate Sleepio towards its proposed Indications for Use. This validation reasonably assures that Sleepio is substantially equivalent to the predicate device. Further, Sleepio met all of the Special Controls per the requirements of the regulation (21 CFR 882.5801). Thus, Sleepio is substantially equivalent to Somryst.