



March 23, 2020

Pear Therapeutics, Inc.  
Yuri Maricich, MD, MBA  
Chief Medical Officer and Head of Development  
201 Mission St. #1450  
San Francisco, California 94105

Re: K191716

Trade/Device Name: Somryst

Regulation Number: 21 CFR 882.5801

Regulation Name: Computerized Behavioral Therapy Device For Psychiatric Disorders

Regulatory Class: Class II

Product Code: PWE

Dated: February 26, 2020

Received: February 27, 2020

Dear Dr. Maricich:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vivek Pinto, PhD  
Director  
DHT5B: Division of Neuromodulation  
and Physical Medicine 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

510(k) Number (if known)

K191716

Device Name

Somryst

Indications for Use (Describe)

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.

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 K191716

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for Somryst is provided below.

### 1. SUBMITTER

<b>Applicant</b>	Pear Therapeutics, Inc. 201 Mission St. #1450 San Francisco, CA 94105 Tel: 617-932-7108 Fax: N/A
<b>Contact</b>	Yuri Maricich, MD, MBA Chief Medical Officer and Head of Development Ph: 206-369-9784 E-mail: <a href="mailto:yuri.maricich@peartherapeutics.com">yuri.maricich@peartherapeutics.com</a>
<b>Submission Contact</b>	Stephen Sherman Vice President Regulatory Affairs Ph: 617-456-7682 E-mail: <a href="mailto:Stephen.Sherman@peartherapeutics.com">Stephen.Sherman@peartherapeutics.com</a>
<b>Date Prepared</b>	25 February 2020

### 2. DEVICE

<b>Device Trade Name</b>	Somryst™
<b>Device Common Name</b>	Prescription digital therapeutic for chronic insomnia
<b>Classification Name</b>	21 CFR 882.5801 Computerized behavioral therapy device for psychiatric disorders
<b>Regulatory Class</b>	II
<b>Product Code</b>	PWE

### 3. PREDICATE DEVICE

<b>Sponsor</b>	Pear Therapeutics, Inc.
<b>Product</b>	reSET®
<b>Regulatory Filing</b>	DEN160018

#### **4. DEVICE DESCRIPTION**

Somryst is a 9-week prescription digital therapeutic (computerized behavioral therapy) used in the treatment of chronic insomnia. Somryst is based on principles of Cognitive Behavioral Therapy (CBT) for Insomnia, Sleep Restriction, and other proven psychosocial treatment elements, which are delivered in a sequence of “cores” of patient education, training and skill building. The therapy is delivered via a mobile application intended to be used on a patient’s mobile device and consists of text, video, animation and graphics. Clinicians, as part of a patient’s general treatment program, have access to a clinician dashboard that shows patient utilization and engagement with the application.

#### **5. INTENDED USE/ INDICATIONS FOR USE**

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.

#### **6. SUBSTANTIAL EQUIVALENCE**

Somryst is a prescription digital therapeutic that is considered a computerized behavioral therapy device for a psychiatric disorder (chronic insomnia) per 21 CFR 882.5801, like reSET®, the proposed predicate from Pear Therapeutics. Somryst shares the same Intended Use, and differs in Indications for Use, as it is used in patients with chronic insomnia instead of Substance Use Disorder (SUD) like the predicate. However, the differences in indications do not represent a new Intended Use, as they are related only to the different psychiatric disorder being treated and the different standard of care in each patient population as compared to the predicate.

Somryst and reSET have similar technological characteristics. They are both comprised of a patient-facing mobile medical application to deliver a form of Cognitive Behavioral Therapy and a clinician dashboard to facilitate patient management, tracking, and clinical decision-making, have substantially similar software architecture and features, utilize the same therapeutic delivery components (text, audio, visuals, video), and are both prescription digital therapeutic devices. Somryst has the same Intended Use as reSET, and minor differences in technological characteristics. The software and clinical validation data demonstrate that Somryst doesn’t raise different types of questions of safety or effectiveness. Thus, considering available performance testing, Somryst is considered substantially equivalent to reSET.

##### **6.1. Intended Use Analysis**

Both the subject device (Somryst) and the predicate device (reSET) are computerized behavioral therapy devices for psychiatric disorders. The products deliver digitized CBT, are deployed through mobile applications for smart devices, have a sequence of content modules with similar behavioral treatment techniques, software architecture, and are both prescription devices. The indications are for different psychiatric disorders; however, this does not constitute a new intended use and thus, reSET can be used as the predicate for Somryst.

## 6.2. Technological Characteristics Comparison

Characteristic	reSET (Predicate)	Somryst (Candidate)
Regulatory Classification	21 CFR 882.5801 Computerized behavioral therapy device for psychiatric disorders.	21 CFR 882.5801 Computerized behavioral therapy device for psychiatric disorders.
Indications for Use	Increase abstinence and retention in patients with Substance Use Disorder (SUD)	Treat patients with chronic insomnia.
Intended User Population	Patients, Licensed healthcare providers (physicians, practitioners, psychologists, and registered nurses)	Patients, Licensed healthcare providers (physicians, practitioners, psychologists, and registered nurses)
Medical Device Type	Software as a Medical Device (SaMD)	Software as a Medical Device (SaMD)
Prescription	Yes	Yes
Software Architecture	Patient facing mobile application, clinician facing dashboard, backend services	Patient facing mobile application, clinician facing dashboard, backend services
Mechanism of Action	Cognitive Behavioral Therapy (for SUD)	Cognitive Behavioral Therapy (for Insomnia)
Software Content	Text, video and audio content	Text, video and audio content
Therapy Duration	12-weeks (90 days)	9-weeks (63 days)
User Interface	Software application that requires users to log in, go through modules of therapeutic content (text, video, audio), interact with device (through quizzes, contingency management, reporting cravings, etc.), and receive prompts/ feedback.	Software application that requires users to log in, go through modules of therapeutic content (text, video, audio), interact with device (through sleep diary and interactive activities, etc.), and receive prompts/ feedback.
Mobile Platform	Smartphones, tablets (iOS and Android)	Smartphones, tablets (iOS and Android)

The minor differences in technological characteristics reflect the different clinical needs for the user populations (chronic insomnia vs. substance use disorder) and the disease-specific CBT for each. These differences do not raise different types of questions of safety and effectiveness.

## 7. PERFORMANCE DATA

### 7.1. Non-clinical Testing

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. Clinical Testing

A responsive browser-based equivalent to Somryst (“SHUTi”) was evaluated in “The GoodNight Study: Prevention of Depression Through Internet-based Insomnia Treatment”, a large-scale, randomized controlled trial (ACTRN12611000121965) sponsored by the National Health and Medical Research Council (NHMRC).[1], [2], [3] This trial was performed by the Australian National University in collaboration with investigators at the Black Dog Institute, University of Sydney, and University of Virginia. The main objective of the study was to evaluate the efficacy of a web-based insomnia intervention, Sleep Healthy Using the Internet (SHUTi) for treatment of patients with chronic insomnia against a control arm of Usual Care (UC) and an attention-matched control (HealthWatch). [1], [2]

All study participants received usual care (UC) consisting of behavioral treatment, pharmacotherapy and/or self-treatment (e.g. visit to a general practitioner for sleep and/or mood problems, pharmacotherapy (e.g. for sleep and/or mood problems), over-the-counter sleep aids, visit to a sleep specialist, visit to a mental health provider).

Participants were randomized 1:1 to 9 weeks of treatment with the following:

- UC+SHUTi: Usual Care + SHUTi (now known as Somryst™)
- UC+Control: Usual Care + Attention-matched, Digital Control

The Digital Control intervention (HealthWatch) was an interactive health and lifestyle web program that contained information about a range of health content (e.g., environmental health, nutrition, activity, medication) but had no specific mental health or sleep-related content. HealthWatch also administered weekly surveys on these topics to match for interaction required in the treatment group.

Participants in the UC+SHUTi group (n=574) were asked to complete all six Cores within the 9-week treatment period. Participants randomized to UC+Control (n=575) were asked to complete nine internet-delivered modules within the 9-week treatment program, thus matching the attention components of SHUTi. Insomnia symptoms were evaluated for all participants at baseline, the end of the 9-week treatment period and the 6-month, 12-month, and 18-month follow-up via the Insomnia Severity Index (ISI) and sleep diaries. Sleep diaries were administered online and collected for a period of 10 days (within a 2-week window), at each assessment time point. Sleep diaries were used to calculate diary-derived composite variables, including sleep onset latency (SOL, minutes to fall asleep) and wake after sleep onset (WASO, minutes awake during the night).

### Insomnia Severity Index (ISI)

Insomnia severity was reduced at both week 9 ( $p<0.0001$ ) and month 6 ( $p<0.0001$ ) among participants who received UC+SHUTi as compared to UC+Control. The average reduction in ISI score was greater at week 9 and month 6 for the UC+SHUTi arm (mean -8.61 and -8.16 respectively) than the UC+Control arm (mean -2.87 and -3.90). The difference between the groups was significant at each timepoint ( $p<0.0001$ ).

An analysis of the proportion of study participants deemed treatment responders and remitters was performed using the ISI data. Responders were defined by demonstration of an ISI score reduction of  $> 7$  points clinically. A reduction of 7 or more points is considered optimal to detect treatment responders as it represents a threshold change in insomnia severity category.[4] Remitters were defined as participants achieving an ISI score of  $< 8$ , a validated cutoff score for insomnia remission.[4] As defined by the ISI, a score ranging between 0 – 7 indicates ‘no clinically

significant insomnia’, a score 8 – 12 indicates ‘subthreshold insomnia’, a score 15 -21 indicates ‘clinical insomnia (moderate severity)’ and a score 22-28 indicates “clinical insomnia (severe)”.<sup>[4][5]</sup>

The proportion of participants in each treatment group deemed treatment responders at week 9, month 6, and month 12 were compared using a chi-square test. Likewise, the proportion of participants in each treatment group deemed treatment remitters at week 9, month 6, and month 12 were compared using a chi-square test.

The proportion of treatment responders identified in each treatment group and their comparison at each timepoint is shown in Table 1. Using criteria of insomnia treatment response (reduction of > 7 points on the ISI from baseline), 62.8% of the UC+SHUTi group were deemed treatment responders from baseline to week 9 compared with 14.0% of the UC+Control group. At the 6 months follow-up, 56.2% of the UC+SHUTi group and 18.9% of the UC+Control group were considered responders. At month 12 follow-up, 59.3% of the UC+SHUTi group and 25.2% of the UC+Control were deemed treatment responders. The difference between treatment groups was significant at all timepoints evaluated ( $p < 0.0001$ ).

*Table 1. Comparison of proportion of ISI responders (reduction in ISI score > 7 points from baseline) by timepoint.*

<b>Time of Assessment</b>	<b>UC+SHUTi Proportion</b>	<b>UC+Control Proportion</b>	<b>P value</b>
<b>End of Treatment Period (Week 9)</b>	157 (62.8%)	48 (14.0%)	<0.0001
<b>Month 6 Follow-up</b>	127 (56.2%)	53 (18.9%)	<0.0001
<b>Month 12 Follow-up</b>	96 (59.3%)	58 (25.2%)	<0.0001

*Note:* p values are not adjusted for multiplicity and analyses are based on available patient data.

A similar pattern was observed for insomnia remitters (Table 2). Using an ISI score of <8 as a cutoff point, 61.6% of the UC+SHUTi group at week 9, 63.7% at month 6, and 63.0% at month 12 were considered insomnia remitters compared with 14.9% of the UC+Control group at week 9, 20.4% at month 6, 25.7% at month 12. The difference between treatment groups (using criteria of either <10 or <8) was significant at every assessment timepoint analyzed ( $p < 0.0001$ ).

*Table 2. Comparison of proportion of ISI remitters (ISI score of < 8) by timepoint.*

<b>Time of Assessment</b>	<b>UC+SHUTi Proportion</b>	<b>UC+Control Proportion</b>	<b>P value</b>
<b>End of Treatment Period (Week 9)</b>	154 (61.6%)	51 (14.9%)	<0.0001
<b>Month 6 Follow-up</b>	144 (63.7%)	57 (20.4%)	<0.0001
<b>Month 12 Follow-up</b>	102 (63.0%)	59 (25.7%)	<0.0001

*Note:* p values are not adjusted for multiplicity and analyses are based on available patient data.

The percentage of participants that achieved a clinically meaningful insomnia treatment response or remission was higher among participants using UC+SHUTi, demonstrating efficacy of UC+SHUTi, compared to UC+Control.



## Effectiveness Outcomes Summary

A summary of the effect of therapy on change from baseline for chronic insomnia outcomes in the ANU study is provided in Table 3 below.

Table 3. Summary of ANU Study effect of therapy on change from baseline at the end of the treatment period (week 9) and follow-ups (6 & 12 months).

Assessment	Timepoint	UC+SHUTi		UC+Control		LS Mean Differences (95% CI)	P value
		Number of Subjects	LS Mean	Number of Subjects	LS Mean		
ISI	End of Treatment Period (Week 9)	250	-8.63	342	-2.85	-5.78 (-6.50, -5.06)	<0.0001
	Month 6 Follow-up	226	-8.17	280	-3.86	-4.31 (-5.09, -3.53)	<0.0001
	Month 12 Follow-up	162	-8.21	230	-4.63	-3.59 (-4.46, -2.71)	<0.0001
SOL	End of Treatment Period (Week 9)	124	-22.7	131	-0.46	-22.4 (-29.7, -15.1)	<0.0001
	Month 6 Follow-up	161	-22.6	201	-7.88	-15.1 (-21.2, -9.09)	<0.0001
	Month 12 Follow-up	130	-27.6	191	-10.8	-17.2 (-23.0, -11.3)	<0.0001
WASO	End of Treatment Period (Week 9)	124	-28.8	131	-11.0	-18.8 (-24.7, -13.0)	<0.0001
	Month 6 Follow-up	161	-27.6	201	-12.5	-15.6 (-21.1, -10.1)	<0.0001
	Month 12 Follow-up	130	-25.1	191	-9.36	-16.5 (-23.1, -9.91)	<0.0001

Note: p values are not adjusted for multiplicity and analyses are based on available patient data.

Data from the Pivotal Trial – UVA also supports to the proposed indications of use. This additional pivotal trial, NCT01438697, is an investigator-initiated study, funded by the National Institute of Mental Health (NIMH) and titled “An Internet Intervention for Insomnia: Efficacy and Dissemination.”[6] The randomized controlled trial of 303 adults with chronic insomnia was led by investigators at the University of Virginia (UVA Study).[6]

Study participants (n=303) were between the ages of 21-65, with sleep-onset insomnia and/or sleep maintenance insomnia (>30 minutes for at least 3 nights/week), insomnia symptoms lasting at least 6 months, an average total sleep time ≤ 6.5 hours per night, and reported significant distress or impairment in social, occupational, or other areas of functioning caused by sleep disturbances (or associated daytime fatigue).

All study participants received Usual Care (UC) consisting of behavioral treatment, pharmacotherapy and/or self-treatment (e.g., visit to a general practitioner for sleep and/or mood (e.g. pharmacotherapy (e.g., for sleep and/or mood problems), over-the-counter sleep aids, visit to a sleep specialist, visit to a mental health provider. The Digital Control program provided access to nontailored and fixed digital material about insomnia symptoms; the effect, prevalence, and causes of insomnia; when to see a physician; and basic lifestyle, environmental, and behavioral strategies to improve sleep.

The evaluation of safety and effectiveness of SHUTi to improve sleep, perceived health status, and overall quality of life was evaluated. Participants were randomized 1:1 to 9 weeks of treatment with

one of the following:

- UC+SHUTi: Usual Care + SHUTi
- UC+Control: Usual Care + digital patient education for insomnia

Participants in the UC+ SHUTi group (n=151) were asked to complete all six Cores within the 9-week treatment period. Participants randomized to UC+Control (n=152) were able to read the patient education material immediately upon completion of the baseline assessments and could log in to review the material as often as they desired throughout the treatment period. Insomnia symptoms were evaluated for all participants at baseline, the end of the 9-week treatment period and the 6- and 12-month follow-up via the ISI and sleep diaries. Sleep diaries were administered online and collected for a period of 10 days (within a 2-week window), at each assessment time point. Diaries were used to calculate diary-derived variables, including SOL and WASO.

The primary outcome measures of the study were insomnia symptoms, SOL, and WASO measured via ISI and daily sleep diary data at the end of the 9-week treatment period and the 6- and 12-month follow-up.

Insomnia severity was reduced at both week 9 ( $p<0.0001$ ) and month 6 ( $p<0.0001$ ) among participants who received UC+SHUTi as compared to UC+Control. The average reduction in ISI score was greater at week 9 and month 6 Follow-Up for the UC+SHUTi arm (mean -7.83 and -8.52 respectively) than the UC+Control arm (mean -2.94 and -5.36, respectively). The difference between the groups was significant at each timepoint ( $p<0.0001$ ).

An analysis of the proportion of study participants deemed treatment responders and remitters was performed using the ISI data. Responders were defined by demonstration of an ISI score reduction of > 7 points clinically. A reduction of 7 or more points is considered optimal to detect treatment responders as it represents a threshold change in insomnia severity category.[4] Remitters were defined as participants achieving an ISI score of < 8, a validated cutoff score for insomnia remission.[4] As defined by the ISI, a score ranging between 0 – 7 indicates ‘no clinically significant insomnia’, a score 8 – 12 indicates ‘subthreshold insomnia’, a score 15 -21 indicates ‘clinical insomnia (moderate severity)’ and a score 22 - 28 indicates “clinical insomnia (severe)”. [4], [5]

The proportion of participants in each treatment group deemed treatment responders at week 9, month 6, and month 12 were compared using a chi-square test. Likewise, the proportion of participants in each treatment group deemed treatment remitters at week 9, month 6, and month 12 were compared using a chi-square test.

The proportion of treatment responders identified in each treatment arm and their comparison at each time point is shown in Table 4. Using criteria of insomnia treatment response (reduction of >7 points on the ISI from baseline), 52.6% of the UC+SHUTi arm were deemed treatment responders at week 9 compared with 16.9% of the UC+Control arm. At month 6 follow-up, 59.6% of the UC+SHUTi arm and 35.7% of the UC+Control arm were considered responders. At month 12 follow-up, 69.7% of the UC+SHUTi arm and 43.0% of the UC+Control arm were deemed treatment responders. The difference between treatment groups was significant at all timepoints evaluated.

Table 4. Comparison of proportion of ISI responders (reduction in ISI score > 7 points from baseline) by timepoint.

Time of Assessment	UC+SHUTi Proportion	UC+Control Proportion	P value
End of Treatment Period (Week 9)	70 (52.6%)	24 (16.9%)	<0.0001
Month 6 Follow-up	68 (59.6%)	46 (35.7%)	0.0002
Month 12 Follow-up	85 (69.7%)	55 (43.0%)	<0.0001

Note: p values are not adjusted for multiplicity and analyses are based on available patient data.

A similar pattern was observed for insomnia remittance (Table 5). Using an ISI score of <8 as a cutoff point, 40.6% of the UC+SHUTi arm at week 9, 49.1% at month 6, and 56.6% at month 12 were considered insomnia remitters compared with 11.3% of the UC+Control arm at week 9, 24.0% at month 6, and 27.3% at month 12. The difference between treatment groups (using criteria of either <10 or <8) was significant at every assessment timepoint analyzed.

Table 5. Comparison of proportion of ISI remitters (ISI score of < 8) by timepoint.

Time of Assessment	UC+SHUTi Proportion	UC+Control Proportion	P value
End of Treatment Period (Week 9)	54 (40.6%)	16 (11.3%)	<0.0001
Month 6 Follow-up	56 (49.1%)	31 (24.0%)	<0.0001
Month 12 Follow-up	69 (56.6%)	35 (27.3%)	<0.0001

Note: p values are not adjusted for multiplicity and analyses are based on available patient data.

The percentage of participants that achieved a clinically meaningful insomnia treatment response or remission was higher among participants using UC+SHUTi, demonstrating efficacy of UC+SHUTi, compared to UC+Control.

## Effectiveness Outcomes Summary

A summary of effect of therapy on change from baseline for chronic insomnia outcomes in the UVA Study is provided in Table 6 below.

Table 6. Summary of UVA Study effect of therapy on change from baseline in chronic insomnia outcomes as assessed at the end of the treatment period (week 9) and follow-ups (6 & 12 months).

Assessment	Timepoint	UC+SHUTi		UC+Control		LS Mean Differences (95% CI)	P value
		Number of Subjects	LS Mean	Number of Subjects	LS Mean		
ISI	End of Treatment Period (Week 9)	133	-7.83	142	-2.94	-4.89 (-6.02, -3.75)	<0.0001
	Month 6 Follow-up	114	-8.52	129	-5.36	-3.16 (-4.41, -1.91)	<0.0001
	Month 12 Follow-up	122	-9.57	128	-6.04	-3.52 (-4.87, -2.18)	<0.0001
SOL	End of Treatment Period (Week 9)	128	-21.5	130	-8.84	-12.6 (-18.3, -6.92)	<0.0001
	Month 6 Follow-up	113	-21.1	123	-13.9	-7.25 (-13.9, -0.62)	0.0323
	Month 12 Follow-up	121	-23.7	127	-16.3	-7.32 (-13.7, -0.90)	0.0255
WASO	End of Treatment Period (Week 9)	128	-24.9	130	-8.46	-17.2 (-24.3, -9.97)	<0.0001
	Month 6 Follow-up	113	-23.9	123	-12.9	-12.1 (-19.2, -5.01)	0.0006
	Month 12 Follow-up	121	-28.4	127	-16.8	-12.7 (-18.9, -6.51)	<0.0001

Note: p values are not adjusted for multiplicity and analyses are based on available patient data.

No participant-reported Adverse Events (AEs) were reported in either study.

## 8. CONCLUSION

Somryst and the predicate reSET have the same Intended Use as computerized behavioral therapy devices for psychiatric disorders. Differences in indications for use are due to differences in clinical needs to the different patient populations but this does not constitute a new intended use. Somryst has similar technological characteristics to reSET, including software architecture, delivery of digitized behavioral therapy through a mobile application, and therapeutic content. Differences in content delivery sequence is due to the unique need for Somryst to collect patient data for sleep diaries, part of CBT-I (but not for CBT for SUD).

Software testing and pivotal clinical study results validate Somryst towards its proposed Indications for Use. This validation reasonably assures that Somryst is substantially equivalent to the predicate device. Further, Somryst met all of the Special Controls per the requirements of the regulation (21 CFR 882.5801).

Thus, Somryst is substantially equivalent to reSET.

## 9. REFERENCES

- [1] J. A. Gosling *et al.*, “The GoodNight study--online CBT for insomnia for the indicated prevention of depression: study protocol for a randomized controlled trial,” *Trials*, vol. 15, no. 1, p. 56, Feb. 2014.
- [2] H. Christensen *et al.*, “Effectiveness of an online insomnia program (SHUTi) for prevention of depressive episodes (the GoodNight Study): A randomised controlled trial,” *The Lancet Psychiatry*, vol. 3, no. 4, pp. 333–341, 2016.
- [3] Batterham PJ, Christensen H, Mackinnon AJ, et al. Trajectories of change and long-term outcomes in a randomised controlled trial of internet-based insomnia treatment to prevent depression. *BJPsych Open*. 2017;3(5):228–235. Published 2017 Sep 25. doi:10.1192/bjpo.bp.117.005231
- [4] C. M. Morin, G. Belleville, L. Bélanger, and H. Ivers, “The insomnia severity index: Psychometric indicators to detect insomnia cases and evaluate treatment response,” *Sleep*, 2011.
- [5] C. H. Bastien, A. Vallières, and C. M. Morin, “Validation of the insomnia severity index as an outcome measure for insomnia research,” *Sleep Med.*, 2001.
- [6] L. M. Ritterband *et al.*, “Effect of a web-based cognitive behavior therapy for insomnia intervention with 1-year follow-up: A randomized clinical trial,” *JAMA Psychiatry*, 2017.