



August 30, 2024

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

Re: K233872

Trade/Device Name: Daylight

Regulation Number: 21 CFR 882.5801

Regulation Name: Computerized Behavioral Therapy Device For Psychiatric Disorders

Regulatory Class: Class II

Product Code: SCP

Dated: August 1, 2024

Received: August 1, 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,

Pamela D. Scott -S

Pamela D. 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

Indications for Use

510(k) Number (if known)
K233872

Device Name
Daylight

Indications for Use (Describe)

Daylight is a prescription device delivering Cognitive Behavioral Therapy and can be made available on the order of a licensed healthcare provider. Daylight is a digital therapeutic intended to treat generalized anxiety disorder (GAD) by improving a patient's GAD symptoms as an adjunct to usual care in patients aged 22 years and older.

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 - K233872

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. Tali M. Ball, Senior Manager, Clinical Research

2. Device

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

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

Daylight is a digital therapeutic designed to address the symptoms of adults with generalized anxiety disorder (GAD) through the use of Cognitive Behavioral Therapy (CBT) techniques. The Daylight program is has been demonstrated to help improve symptoms of GAD, if followed correctly, and is supported by evidence from peer-reviewed studies and clinical trials. The program is delivered digitally through the Daylight iOS/Android apps, giving users easy access to effective techniques.

5. Intended use / Indications for use

Daylight is a prescription device delivering Cognitive Behavioral Therapy and can be made available on the order of a licensed healthcare provider. Daylight is a digital therapeutic intended to treat generalized anxiety disorder (GAD) by improving a patient's GAD symptoms as an adjunct to usual care in patients aged 22 years and older.

6. Substantial equivalence

Daylight has an identical intended use and nearly identical technological characteristics compared to the predicate device, Somryst. Like Somryst, Daylight delivers cognitive behavioral therapy for treatment of psychiatric disorders by way of an app provided as an adjunct to usual care by the patient’s healthcare provider. The specific indication differs, in that Daylight is indicated for use in treatment of generalized anxiety disorder (GAD), not insomnia disorder. 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. The software and clinical validation data demonstrate that Daylight doesn’t raise different types of questions of safety or effectiveness. Thus, considering available performance testing, Daylight is considered substantially equivalent to Somryst.

Table 1: Substantial Equivalence Assessment

Category	Daylight (this submission)	Somryst (predicate)
510(k) number	K233872	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 generalized anxiety disorder (GAD)	SaMD intended to be computerized behavioral therapy device to treat patients with chronic insomnia
Indications for use	Daylight is a digital therapeutic intended for the treatment of generalized anxiety disorder as an adjunct to usual care in patients aged 22 years and older. Daylight is a prescription device delivering Cognitive Behavioral Therapy 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
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)
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])	Mobile application (Smartphones, tablets [iOS and Android])
Software architecture	Patient facing mobile application, clinician facing dashboard, backend services	Patient facing mobile application, clinician facing dashboard, backend services
Software safety classification	Class B	Class B

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

Daylight was evaluated in the Generalized Anxiety Therapy Effectiveness (GATE) trial which was a two-arm, parallel group, randomized controlled trial (RCT) comparing digital CBT (Daylight) with online anxiety psychoeducation in 351 adults aged 22+ with generalized anxiety disorder (GAD). Participants were recruited from across the United States via social media. Participants with a diagnosis of GAD according to DSM-5 were allocated to receive Daylight (n=175) or online anxiety psychoeducation (n=176), using a blind-to-hypothesis approach.

Although psychoeducation and Daylight have some differences in format and interactivity, the psychoeducation control used in the GATE trial matched Daylight on key characteristics including human contact, self-pacing, and retention. Although Daylight included more content separated into modules and required more time to complete, both groups were able to access all of the content immediately and neither treatment was time-locked. In prior research¹ on the Daylight device and the same psychoeducation treatment, psychoeducation has also been shown to match Daylight on patient perceptions of credibility and expectation of benefit (Table 2).

Table 2. Patient credibility and expectancy of Psychoeducation and Daylight

	Psychoeducation	Daylight
Credibility	22.0 (SD = 3.8)	19.5 (SD = 4.0)
Expectancy (average expected symptom reduction)	32%	39%

¹ Carl et al (2020). Efficacy of digital cognitive behavioral therapy for moderate-to-severe symptoms of generalized anxiety disorder: A randomized controlled trial. *Depression and Anxiety*, 37(12), 1168–1178. <https://doi.org/10.1002/da.23079>; and additional unpublished internal data

Note: SD = standard deviation.

The co-primary outcome measures were remission based on the Clinical Global Impression - Improvement scale (CGI-I) scores of 1 or 2 and patient-reported generalized anxiety symptom severity, assessed using the generalized anxiety disorder 7-item questionnaire (GAD-7). The primary endpoint was 10 weeks post-randomization and a follow-up assessment occurred at 24 weeks post-randomization. Secondary outcomes included depression symptoms assessed by the Patient Health Questionnaire (PHQ-8), insomnia symptoms assessed by the Sleep Condition Indicator (SCI-8), and anxiety severity assessed by the Clinical Global Impression - Severity (CGI-S) scale and the patient-reported Overall Anxiety Severity and Impairment Scale (OASIS).

Across the total sample, 24% of participants (23% Daylight and 25% Control) were taking concomitant prescription anxiety medications at baseline, and 18% of participants (19% Daylight, 18% Control) were taking non-prescription substances to target anxiety. In addition, 4% of participants reported having seen a treatment provider for anxiety in the 3 weeks prior to their baseline assessment (4% Daylight, 4.5% Control), and 41% of participants reported previous therapy experience (38% Daylight, 43% Control).

A summary of the results of the GATE trial for Daylight vs psychoeducation is provided in Tables 3 and 4 and Figure 1 below.

Table 3: GAD-7 scores from the GATE trial, including summary statistics by group and time, and estimated treatment effects (i.e., adjusted differences)

	Unadjusted mean (SD)		Adjusted difference (95% CI)	Cohen's <i>d</i>	<i>p</i> -value
	Daylight	Psychoeducation Control			
Baseline	15.58 (3.50) n = 175	16.14 (3.07) n = 176	N/A	N/A	N/A
Week 6	8.82 (4.50) n = 159	12.45 (4.35) n = 170	3.42 (2.50, 4.34)	1.04	p<0.001
Week 10	7.88 (4.76) n = 157	11.68 (4.42) n = 168	3.58 (2.66, 4.50)	1.09	p<0.001
Week 24	7.23 (4.88) n = 156	10.68 (4.73) n = 166	3.15 (2.21, 4.09)	0.96	p<0.001

Note: CI=Confidence Interval; SD=Standard Deviation

Figure 1. GAD-7 scores from the GATE trial through 24 weeks post randomization. Error bars = standard error of the mean. *** p<0.001

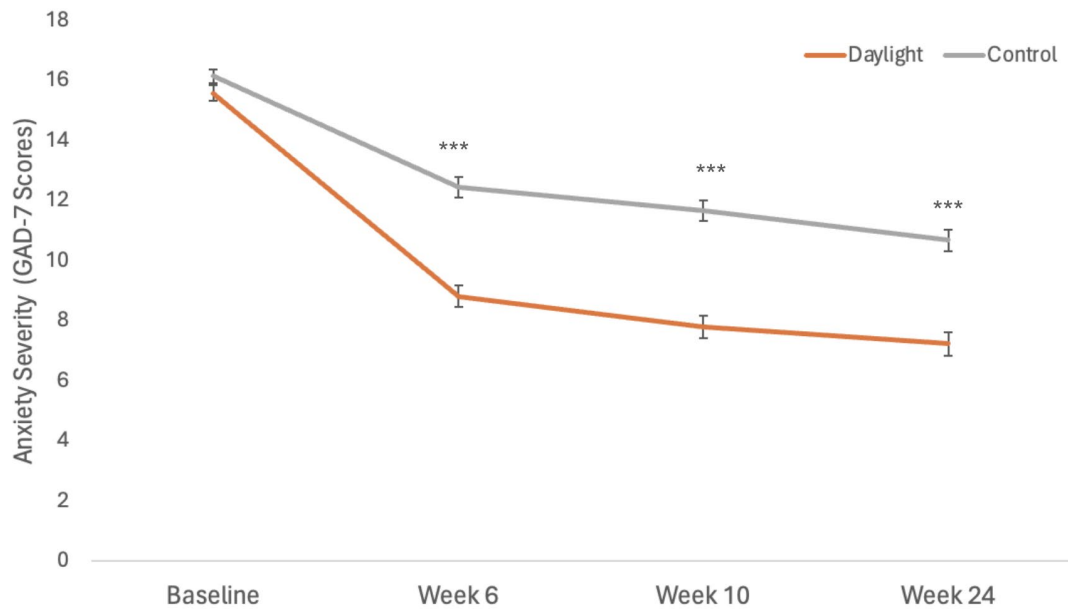


Table 3: CGI-I based remission rates from the GATE trial

	N (% of group)		OR; p-value (95% CI)
	Daylight	Psychoeducation Control	
Week 10 – No	42 (29%)	102 (65%)	4.63; p<0.001 (2.85, 7.54)
Yes	103 (71%)	54 (35%)	
Week 24 – No	33 (22%)	72 (48%)	3.22; p<0.001 (1.95, 5.32)
Yes	115 (78%)	78 (52%)	

Note: Remission defined as CGI-I score of 1 or 2; OR > 1 indicates greater odds of remission in Daylight than Psychoeducation Control; OR = Odds Ratio; CI=Confidence Interval.

One adverse event was rated “probably” related to Daylight use during the treatment period: worsening panic attack severity. Adverse events that were rated “possibly” related to Daylight use were: panic attacks (n=4 [2.3%]), depression symptoms (n=5 [2.9%]), pre-menstrual/post-partum/seasonal mood symptoms (n=3 [1.7%]), thoughts of death or suicide (n=3 [1.7%]), PTSD symptoms (n=1 [0.6%]), musculoskeletal pain (n=6 [3.4%]), and headache (n=3 [1.7%]). Two serious adverse events were reported by study participants in the Daylight arm; neither of these were related to use of Daylight or participation in the trial. There were no unanticipated adverse device effects.

8. Conclusion

Daylight 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 Daylight is indicated for treatment of symptoms of generalized anxiety disorder, but this does not constitute a new intended use. Daylight has similar technological characteristics to Somryst, including software architecture and delivery of digital cognitive behavioral therapy through a mobile application. Software testing and pivotal clinical study results validate Daylight towards its proposed Indications for Use. This validation reasonably assures that Daylight is substantially equivalent to the predicate device. Further, Daylight met all of the Special Controls per the requirements of the regulation (21 CFR 882.5801). Thus, Daylight is substantially equivalent to Somryst.