



November 6, 2020

NightWare, Inc
% Amy Fowler
Regulatory Counsel
Pathmaker FDA Law
528 Hennepin Avenue, Suite 503
Minneapolis, Minnesota 55403

Re: DEN200033

Trade/Device Name: NightWare Kit (Apple iPhone, Apple Watch, Apple iPhone Charging Cable,
Apple Watch Charging Cable)

Regulation Number: 21 CFR 882.5705

Regulation Name: Digital therapy device to reduce sleep disturbance for psychiatric conditions

Regulatory Class: Class II

Product Code: QMZ

Dated: May 22, 2020

Received: May 27, 2020

Dear Amy Fowler:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the NightWare Kit (Apple iPhone, Apple Watch, Apple iPhone Charging Cable, Apple Watch Charging Cable), a prescription device under 21 CFR Part 801.109 with the following indications for use:

The NightWare digital therapeutic is indicated to provide vibrotactile feedback on an Apple Watch based on an analysis of heart rate and motion during sleep for the temporary reduction of sleep disturbance related to nightmares in adults 22 years or older who suffer from nightmare disorder or have nightmares from posttraumatic stress disorder (PTSD). It is intended for home use.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the NightWare Kit, and substantially equivalent devices of this generic type, into Class II under the generic name digital therapy device to reduce sleep disturbance for psychiatric conditions.

FDA identifies this generic type of device as:

Digital therapy device to reduce sleep disturbance for psychiatric conditions. A digital therapy device to reduce sleep disturbance for psychiatric conditions is a prescription device that is intended to provide stimulation using a general purpose computing platform to reduce sleep disturbance in patients who experience this symptom due to psychiatric conditions such as nightmare disorder or post traumatic stress disorder (PTSD).

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On May 27, 2020, FDA received your De Novo requesting classification of the NightWare Kit. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the NightWare Kit into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the NightWare Kit can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risks to Health	Mitigation Measures
Ineffective treatment leading to worsening sleep	Clinical performance testing
Ineffective treatment leading to worsening condition-specific symptoms	Clinical performance testing
Device software failure leading to delayed access and treatment	Software verification, validation, and hazard analysis
Improper device use leading to worsening sleep	Labeling

In combination with the general controls of the FD&C Act, the digital therapy device to reduce sleep disturbance for psychiatric conditions is subject to the following special controls:

- (1) Clinical performance testing under the labeled conditions for use must evaluate the following:
 - (i) The ability of the device to provide therapy for patients with sleep disturbance due to psychiatric conditions, using a validated measure;
 - (ii) Worsening of any condition-specific symptoms using a validated measure for assessment of the particular condition; and
 - (iii) Increase in symptoms of disturbed sleep or sleepiness using a validated measure.
- (2) Software must clearly describe all features and functions of the software implementing the digital therapy. Software verification, validation, and hazard analysis must also be provided.
- (3) The labeling must include the following:

- (i) Patient and physician labeling must include instructions for use, including images that demonstrate how to interact with the device;
- (ii) Patient and physician labeling must list the minimum operating system (OS) and general purpose computing requirements that support the software of the device;
- (iii) Patient and physician labeling must include a warning that the digital therapy device is not intended for use as a standalone therapeutic device;
- (iv) Patient and physician labeling must include a warning that the digital therapy device does not represent a substitution for the patient's medication; and
- (v) Physician labeling must include a summary of the clinical performance testing conducted with the device.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the digital therapy device to reduce sleep disturbance for psychiatric conditions they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Patrick Antkowiak at 240-402-3705.

Sincerely,

Carlos Pena, Ph.D., M.S.
Director
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health