



Food and Drug Administration
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September 14, 2017

Pear Therapeutics, Inc.
Nandini Murthy
Vice-President, Regulatory Affairs
745 Atlantic Ave.
Boston, Massachusetts 02111

Re: DEN160018
Trade/Device Name: reSET
Regulation Number: 21 CFR 882.5801
Regulation Name: Computerized behavioral therapy device for psychiatric disorders
Regulatory Class: Class II
Product Code: PWE
Dated: May 12, 2016
Received: May 16, 2016

Dear Nandini Murthy:

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 reSET, a prescription device under 21 CFR Part 801.109 with the following indications for use:

reSET is intended to provide cognitive behavioral therapy, as an adjunct to a contingency management system, for patients 18 years of age and older who are currently enrolled in outpatient treatment under the supervision of a clinician. reSET is indicated as a 12 week (90 days) prescription-only treatment for patients with substance use disorder (SUD), who are not currently on opioid replacement therapy, who do not abuse alcohol solely, or who do not abuse opioids as their primary substance of abuse. It is intended to:

- increase abstinence from a patient's substances of abuse during treatment, and
- increase retention in the outpatient treatment program.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the reSET, and substantially equivalent devices of this generic type, into Class II under the generic name computerized behavioral therapy device for psychiatric disorders.

FDA identifies this generic type of device as:

Computerized behavioral therapy device for psychiatric disorders. A computerized behavioral therapy device for psychiatric disorders is a prescription only device intended

to provide a computerized version of condition-specific behavioral therapy as an adjunct to clinician supervised outpatient treatment to patients with psychiatric conditions. The digital therapy is intended to provide patients access to therapy tools used during treatment sessions to improve recognized treatment outcomes.

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 new 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, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. 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 classifying the device type.

On May 16, 2016, FDA received your De Novo requesting classification of the reSET. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the reSET 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 reSET 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:

Identified Risk	Mitigation Measures
Device provides ineffective treatment, leading to worsening condition	Clinical data Software verification, validation, and hazard analysis Labeling
Device software failure, leading to delayed access	Software verification, validation, and hazard analysis Labeling
Use error / improper device use	Labeling

In combination with the general controls of the FD&C Act, the computerized behavioral therapy device for psychiatric disorders is subject to the following special controls:

1. Clinical data must be provided to fulfill the following:
 - a. Describe a validated model of behavioral therapy for the psychiatric disorder; and
 - b. Validate the model of behavioral therapy as implemented by the device.
2. Software must be described in detail in the software requirements specification (SRS) and software design specification (SDS). Software verification, validation, and hazard analysis must be performed. Software documentation must demonstrate that the device effectively implements the behavioral therapy model.
3. The following labeling must be provided:
 - a. Patient and physician labeling must include instructions for use, including images that demonstrate how to interact with the device.
 - b. Patient and physician labeling must list compatible devices.
 - c. Patient and physician labeling must include a warning that the device is not intended for use as a standalone therapy.
 - d. Patient and physician labeling must include a warning that the device does not represent a substitution for the patient's medication.
 - e. Physician labeling must include a summary of the clinical testing with the device.

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

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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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.

If you have any questions concerning the contents of the letter, please contact Patrick Antkowiak at 240-402-3705 or please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100, or at its internet address:

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

Angela C. Krueger
Deputy Director,
Engineering and Science Review (Acting)
Office of Device Evaluation
Center for Devices and Radiological Health