



May 23, 2019

Pear Therapeutics, Inc.  
Nandini Murthy  
Regulatory Consultant to Pear Therapeutics, Inc.  
745 Atlantic Ave.  
Boston, Massachusetts 02111

Re: K173681

Trade/Device Name: reSET-O  
Regulation Number: 21 CFR 882.5801  
Regulation Name: Computerized behavioral therapy device for psychiatric disorders  
Regulatory Class: Class II  
Product Code: PWE  
Dated: August 21, 2019  
Received: August 22, 2018

Dear Nandini Murthy:

This letter corrects our substantially equivalent letter of December 10, 2018.

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/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,

Carlos Pena, PhD, MS  
Director  
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)

K173681

Device Name

reSET-O

Indications for Use (Describe)

reSET-O™ is intended to increase retention of patients with opioid use disorder (OUD) in outpatient treatment by providing cognitive behavioral therapy, as an adjunct to outpatient treatment that includes transmucosal buprenorphine and contingency management, for patients 18 years or older who are currently under the supervision of a clinician. reSET-O is indicated as a prescription-only digital therapeutic.

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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**Pear Therapeutics, Inc.**

Traditional 510(k) Premarket Notification Submission – reSET-O

**510(k) SUMMARY**

**Submitter Name:** Pear Therapeutics, Inc.

**Submitter Address:** 201 Mission St., San Francisco, CA 94710

**Contact Person:** Yuri Maricich

**Phone Number:** (206) 369-9784

**Submission Correspondent:** David Amor

**Phone Number:** (786) 546-1806

**Date Prepared:** November 19, 2018

**Device Trade Name:** reSET-O

**Device Common Name:** Prescription Digital Therapeutic

**Classification regulation:** 21 CFR 882.5801, Class II Product Code PWE

**Predicate Device:** reSET, DEN160018

**Classification Name:** Computerized Behavioral Therapy Device for Psychiatric Disorders

**Device Description:**

reSET-O™ is a 12-week interval prescription digital therapeutic for Opioid Use Disorder (OUD). reSET-O™ is modeled on the Community Reinforcement Approach (CRA) and engineered to deliver behavioral therapy for patients with OUD. reSET-O™ delivers CRA therapy as a series of interactive therapy lessons. Each therapy lesson is comprised of a cognitive behavioral therapy component and skill building exercises. Therapy lesson content is delivered primarily via text or audio, and may include videos, animations and graphics.

reSET-O™ is intended as an adjunct to standard of care for patients with OUD. It is limited to persons with a valid prescription from their licensed provider. reSET-O™ supports clinician-patient communication between visits, by providing a means for patients to self-report cravings and triggers, and buprenorphine use/non-use. reSET-O™ reinforces the importance of using buprenorphine for treatment of OUD.

**Pear Therapeutics, Inc.**

Traditional 510(k) Premarket Notification Submission – reSET-O

**Indications for Use:**

reSET-O™ is intended to increase retention of patients with opioid use disorder (OUD) in outpatient treatment by providing cognitive behavioral therapy, as an adjunct to outpatient treatment that includes transmucosal buprenorphine and contingency management, for patients 18 years or older who are currently under the supervision of a clinician. reSET-O is indicated as a prescription-only digital therapeutic.

**Rationale for Substantial Equivalence:** Comparison of reSET-O versus predicate

<b>Characteristics</b>	<b>reSET-O <u>K173681</u></b>	<b>reSET (Predicate) DEN160018</b>
<b>Product Code</b>	21 CFR 882.5801 PWE	21 CFR 882.5801 PWE
<b>Intended Use</b>	Intended to increase retention in patients with Opioid Use Disorder (OUD)	Intended to increase abstinence and retention in patients with Substance Use Disorder (SUD)
<b>Indications for Use</b>	reSET-O™ is intended to increase retention of patients with opioid use disorder (OUD) in outpatient treatment by providing cognitive behavioral therapy, as an adjunct to outpatient treatment with transmucosal buprenorphine and contingency management, for patients 18 years or older who are currently under the supervision of a clinician. reSET-O is indicated as a prescription-only digital therapeutic.	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: <ul style="list-style-type: none"><li>• increase abstinence from a patient’s substances of abuse during treatment, and</li><li>• increase retention in the outpatient treatment program.</li></ul>

**Pear Therapeutics, Inc.**

Traditional 510(k) Premarket Notification Submission – reSET-O

<b>Characteristics</b>	<b>reSET-O <u>K173681</u></b>	<b>reSET (Predicate) DEN160018</b>
<b>System components</b>	Patient facing app, mobile device platform Clinician facing app, PC/web platform	Patient facing app, mobile device platform Clinician facing app, PC/web platform
<b>Access</b>	Rx only	Rx only
<b>Users</b>	Patients with an opioid use disorder.	Patients with a substance use disorder who are not currently on opioid replacement therapy, abuse alcohol solely or whose primary substance of abuse is opioids.
<b>Contingency Management</b>	Yes	Yes
<b>Adjunctive application</b>	Yes - to Treatment as Usual (TAU), that includes transmucosal buprenorphine in addition to outpatient treatment and contingency management	Yes - to Treatment as Usual (TAU), that includes outpatient treatment and contingency management

reSET-O™ and reSET® are both prescription devices, with similar application for use in an outpatient treatment program (standard of care). Retention in the program is a key goal in outpatient treatment for any substance use disorder. Both reSET and reSET-O are adjunctive to standard of care. The only difference with the standard of care for patients with OUD (reSET-O™) is that it includes pharmacotherapy (buprenorphine) along with outpatient treatment.

**Performance Data:**

Bench data: The results of bench software verification and validation testing supports that reSET-O functions as intended.

Clinical data: reSET-O was validated to meet its intended use in a randomized clinical trial<sup>1</sup> (Clinical Trials identifier, NCT00929253). The study enrolled 170 patients seeking treatment for OUD. All study participants met DSM-IV criteria for opioid dependence

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<sup>1</sup> Christensen DR, Landes RD, Jackson L, et al. Adding an Internet-delivered treatment to an efficacious treatment package for opioid dependence. J Consult Clin Psychol. 2014;82(6):964-972. doi:10.1037/a0037496

**Pear Therapeutics, Inc.**

Traditional 510(k) Premarket Notification Submission – reSET-O

and qualified for buprenorphine treatment. Patients were randomized to 12-weeks of treatment as usual (TAU) or TAU plus (Therapeutic Educational System) TES. TAU included thrice-weekly in-person administration of buprenorphine treatment<sup>2</sup>, thrice-weekly urine testing, contingency management system, and a face to face visit with a clinician every other week. The primary outcome was abstinence defined as the longest documented period of continuous abstinence from opioids and cocaine for each participant.

The results of the clinical study demonstrates that treatment dropout during the 12-week intervention was reduced in the TES group compared to the TAU group. The dropout rate in the TES group was 17.6% compared to 31.6% in the TAU group, with a p-value of 0.0224. This reduction in treatment dropout was significant.

Abstinence was evaluated for trend over 12 weeks in the three times a week Urine Drug Screen (UDS). The ability of reSET-O to improve abstinence has not been established as clinically significant.

Adverse events were collected and monitored throughout the study, and showed that there was no difference in AE rates between the TES and TAU groups.

**Conclusion:**

reSET-O has similar indications statements as the predicate device. Both devices are used to provide computerized behavioral therapy to patients suffering from substance use disorder. Both devices are adjunctive to standard of care for patients, intended to provide and reinforce therapy delivered in outpatient treatment. Both devices include self-report features that allow the patient and clinician to recognize patterns related to substance use, triggers and cravings.

Preclinical software testing and pivotal clinical study results validate reSET-O towards its proposed intended use. Further, reSET-O met all of the Special controls per the requirements of the predicate (DEN160018).

Therefore, reSET-O is substantially equivalent to the predicate reSET device.

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<sup>2</sup> Buprenorphine treatment consisted of buprenorphine/naloxone combination administered sublingually (4:1) ratio during the 12-week study