



November 25, 2020

Mahana Therapeutics, Inc.
Jean-Noel Courvoisier
Senior Manager, Regulatory Affairs
230 California Street, Suite 302
San Francisco, CA 94111

Re: DEN200029
Trade/Device Name: Parallel
Regulation Number: 21 CFR 876.5960
Regulation Name: Computerized behavioral therapy device for treating symptoms
of gastrointestinal conditions
Regulatory Class: Class II
Product Code: QMY
Dated: April 29, 2020
Received: April 30, 2020

Dear Jean-Noel Courvoisier:

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

Parallel is a prescription-only digital therapeutic device intended to provide cognitive behavioral therapy for adults aged 22 years of age and older who have been diagnosed with Irritable Bowel Syndrome (IBS). Parallel is indicated as a 3 month treatment for patients with IBS. Parallel treats IBS by reducing the severity of symptoms and is intended to be used together with other IBS treatments.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Parallel, and substantially equivalent devices of this generic type, into Class II under the generic name Computerized behavioral therapy device for treating symptoms of gastrointestinal conditions.

FDA identifies this generic type of device as:

Computerized behavioral therapy device for treating symptoms of gastrointestinal conditions.

A computerized behavioral therapy device for treating symptoms of gastrointestinal conditions is a prescription device intended to provide a computerized version of condition-specific therapy as an adjunct to standard of care treatments to patients with gastrointestinal conditions.

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 April 30, 2020, FDA received your De Novo requesting classification of the Parallel. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Parallel 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 Parallel 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 Risks to Health	Mitigation Measures
Worsening of condition due to device providing ineffective treatment.	Clinical data Labeling
Delayed access to treatment due to device software failure.	Software verification, validation, and hazard analysis Labeling
Ineffective treatment due to use error/ improper use of device	Usability assessment Labeling
Treatment results in anxiety, depressed mood, depression, mental disorder (unspecified), stress or suicidal ideation	Clinical data Labeling

In combination with the general controls of the FD&C Act, the computerized behavioral therapy device for treating symptoms of gastrointestinal conditions is subject to the following special controls:

1. Clinical data must be provided to fulfill the following:
 - i. Describe a model of therapy for the indicated gastrointestinal conditions;
 - ii. Validate the model of therapy as implemented by the device using a clinically defined endpoint; and
 - iii. Evaluate all adverse events.
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. Usability assessment must demonstrate that the intended user(s) can safely and correctly use the device.
4. Labeling must include:
 - i. 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 requirements that support the software of the device;
 - iii. Patient and physician labeling must include a warning that the device is not intended for use in lieu of a standard therapeutic intervention or represent a substitution for the patient's medication;
 - iv. Patient and physician labeling must include a warning to seek medical care if a patient has feelings or thoughts of harming themselves or others; and
 - v. Physician and patient 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.

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 computerized behavioral therapy device for treating symptoms of gastrointestinal 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 Stephanie Cole at 301-796-8587.

Sincerely,

Charles Viviano, M.D., Ph.D.
Acting Director
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health