June 2, 2021

Mahana Therapeutics, Inc.
Jean-Noel Courvoisier
Senior Manager Global Regulatory Affairs
One Market, Spear Tower 36th Floor
San Francisco, CA 94105

Re: K211372
Trade/Device Name: Mahana Parallel Digital Cognitive Behavioral Therapy (CBT) Mobile Application for Irritable Bowel Syndrome (IBS)
Regulation Number: 21 CFR§ 876.5960
Regulation Name: Computerized Behavioral Therapy Device for Treating Symptoms of Gastrointestinal Conditions
Regulatory Class: II
Product Code: QMY
Dated: April 30, 2021
Received: May 4, 2021

Dear Jean-Noel Courvoisier:

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/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 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 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,

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K211372

Device Name

Mahana Parallel Digital Cognitive Behavioral Therapy (CBT) Mobile Application for Irritable Bowel Syndrome (IBS)

Indications for Use *(Describe)*

Parallel™ is a prescription-only digital therapeutic 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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements set forth in 21 CFR 807.92

The assigned 510(k) number is: K211372

Submitter / Company
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Date prepared
26 May 2021

Proposed new device

Trade/Proprietary Name:	Mahana Parallel Digital Cognitive Behavioral Therapy (CBT) Mobile Application for Irritable Bowel Syndrome (IBS)
Common/Usual Name:	Digital Cognitive Behavioral Therapy (CBT) software for Irritable Bowel Syndrome (IBS)
Device Class	Class II
Classification Name	Computerized behavioral therapy device for treating symptoms of gastrointestinal conditions
Predicate Device	Parallel - DEN200029
Regulation Number	21 CFR 876.5960
Product Code	QMY
Device Regulation Panel:	Gastrointestinal

Subject device description
Parallel is a Prescription Digital Therapeutic (PDT) mobile application designed to deliver Cognitive Behavioral Therapy (CBT) to patients with Irritable Bowel Syndrome (IBS). PDTs are a new class of treatment using software to treat medical diseases.

The Parallel CBT program has been tailored for patients with IBS. The rationale for applying CBT to treat IBS is grounded in the biopsychosocial model. This model states that one's biology, thoughts, emotions, and behaviors influence IBS symptom expression in a bidirectional way.[1] The biological substrate of these interactions that affect IBS outcomes is the "brain-gut axis". The brain-gut axis underlies the pathways (e.g., psychological, behavioral functioning, and physiological interactions) that contribute to IBS symptom manifestation.[2] CBT allows patients to influence brain-gut communication in order to reduce the severity of IBS.

Parallel is available by prescription only and is intended to provide 3 months of cognitive behavioral therapy for adult patients, aged 22 years and older, with IBS. Parallel is intended to provide CBT, as an adjunct to any other IBS treatments. The Parallel mobile application uses the patient's mobile phone or tablet to deliver therapy on demand as a complement to the provider's care.

Typical length of the therapy period is 3 months and is composed of ten (10) sessions. The first session explains IBS symptoms, the key features of the brain-gut axis, and the personalization of the rationale for CBT. The next nine (9) sessions provide personalized treatment for IBS by asking patients questions and getting them to complete interactive tasks. Each session contains several pages of content which may be text, audio files, video files, or interactive components. During the program, patients are provided short tasks to complete during the week. Patients are also asked to complete questionnaires from time to time to rate the severity of their IBS symptoms and the impact symptoms are having on their life and mood.

Indication for use
The indication for use of the subject Parallel (mobile version) remains identical that of the predicate Parallel (web version - DEN200029):
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.

Technological characteristic differences
The changes from the predicate device consist of:

- Technical optimization for mobile application environment over web-based software including:
  - Software platform to mobile environment.
  - Web to mobile device user interface form factor.
  - Downloading homework PDF files to interactive in-app homework.
- Minor content adjustments including:
  - Updates to reflect current clinical best practice.
  - Reordering of some contents within sessions.
  - Changes to session breaks for length consistency.
  - Digitization of homework process.

[1] Moss-Morris, R., *et al.* (2010). A randomized controlled trial of a cognitive behavioural therapy-based self management intervention for irritable bowel syndrome in primary care. Psychological medicine, 40(1), 85-94.
[2] van Tilburg, M. A., *et al.* (2013). Which psychological factors exacerbate irritable bowel syndrome? Development of a comprehensive model. Journal of psychosomatic research, 74(6), 486-492.

Clinical tests

The differences between the predicate (Parallel web version) and the subject (Parallel mobile version) devices consist of technological changes and minor adjustments to content.

The core CBT skills that constitute the clinical basis of the predicate Parallel (web version) are unchanged and remain identical in the subject Parallel (mobile version). There is no impact to clinical functionality, and no new introduced or modified existing risks. By following Mahana's Design Control process, it is sufficient to establish substantial equivalence between the web and mobile versions of Parallel. Therefore, no additional clinical studies are necessary to establish substantial equivalence between the web and mobile versions of Parallel, and to provide reasonable assurance of safety and effectiveness.

Non-clinical tests

Following Mahana's design control procedures, verification and validation activities have been completed successfully for Parallel. Parallel software verification passed all tests within the passing criteria with limitations. All open bugs were triaged for risk, documented, and in accordance with ISO14971. All open bugs are either in queue for fix in the current sprint cycle or deferred for a future sprint cycle with justification. All deferred bugs have been documented and found acceptable for risk.

The subject device (Parallel mobile version) was assessed for human factors risk and there were no critical tasks discovered during risk assessment. Parallel (mobile version) passed user usability testing for usability, navigation, functionality, and ability to complete tasks.

In conclusion, the clinical and non-clinical tests demonstrate that the subject device (Parallel mobile version) is as safe, as effective, and performs as well as or better than the legally marketed device predicate (Parallel web version - DEN200029).