July 7, 2023

Better Therapeutics
℅ Allison Komiyama, Vice President of MedTech Innovations
RQM+
2790 Mosside Blvd.
Monroeville, Pennsylvania 15146

Re: DEN220058
Trade/Device Name: BT-001
Regulation Number: 21 CFR 880.5735
Regulation Name: Diabetes digital behavioral therapeutic device
Regulatory Class: Class II
Product Code: QXC
Dated: April 17, 2023
Received: April 18, 2023

Dear Allison Komiyama:

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 BT-001, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> BT-001 is a prescription-only digital therapeutic device intended to provide cognitive behavioral therapy to patients 18 years or older with type 2 diabetes. The device targets behavior to aid in the management of type 2 diabetes in patients who are under the care of a healthcare provider. BT-001 provides cognitive behavioral therapy as a treatment that should be used adjunctively with standard of care.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the BT-001, and substantially equivalent devices of this generic type, into Class II under the generic name diabetes digital behavioral therapeutic device.

FDA identifies this generic type of device as:

> **Diabetes digital behavioral therapeutic device**. A diabetes digital behavioral therapeutic device is a prescription use software device that provides digital behavioral therapy to aid in the management of diabetes. This device is intended to provide limited secondary benefit to patients with diabetes mellitus by assisting them in managing their condition. This device is not intended to replace any primary treatment, such as diet/lifestyle changes or medication.

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 September 21, 2022, FDA received your De Novo requesting classification of the BT-001. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the BT-001 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 BT-001 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:

Risks to Health	**Mitigation Measures**
Worsening of condition due to device providing ineffective treatment	Certain design verification and validation activities, including clinical data Certain labeling information, including certain limiting statements
Treatment results in anxiety, depressed mood, depression, mental disorder (unspecified), stress or suicidal ideation	Certain design verification and validation activities, including clinical data Certain labeling information, including certain limiting statements
Ineffective treatment due to use error / improper use of device / device software failure	Certain labeling information, including certain limiting statements

In combination with the general controls of the FD&C Act, the diabetes digital behavioral therapeutic device is subject to the following special controls:

(1) Design verification and validation must include documentation of:
    (i) Clinical data from a statistically and clinically justified sample size, fulfilling the following:

(A) Appropriately validating the model of therapy as implemented by the device using a clinically defined endpoint, and
(B) Demonstrating that use of the device does not adversely impact the health outcomes or health status of the intended use population. A device hazard analysis must consider all device-related adverse events observed from the clinical data collected and must demonstrate that patient risk from use of the device is minimal.

(ii) Software verification, validation, and hazard analysis must demonstrate that the device performs as intended.

(2) The labeling must include:

(i) A summary of the clinical testing with the device, including a discussion of the limitations of the clinical significance of the results.

(ii) Limiting statements that indicate:

(A) The device is not intended for use as a standalone therapy.
(B) The device is not a substitute for a patient's prescribed therapy or medication.
(C) The device should not be used by people with unstable psychiatric disorders.
(D) The device is not intended for use in the treatment of any psychiatric disorder or symptoms.

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 diabetes digital behavioral therapeutic device 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 Joshua Balsam at 240-402-6521.

Sincerely,

Marianela Perez-torres -S

Marianela Perez-Torres, Ph.D.
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and Toxicology Devices
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