specimen type. Results must be obtained from geographically diverse locations, such that the performance of the test device is appropriately representative of all present, circulating strains of the claimed viral analyte(s) at the time of the study and submission. Additionally, the clinical study must include participants that are representative of the intended use population and across the clinical range of the claimed viral analyte. The clinical study must be performed in the intended use setting (*e.g.,* at home or a home-like environment). The results obtained with the candidate device must be compared to results obtained using a molecular comparator method that FDA has determined to be appropriate. Detailed documentation must include the clinical study protocol (including a predefined statistical analysis plan), study report, testing results, and results of all statistical analyses;

(iii) The clinical study designs, including number of samples tested, must be sufficient such that the lower bound of the two-sided 95 percent confidence interval of the positive percent agreement with the comparator must be greater than 70 percent and additional and appropriate risk mitigation measures are established (*e.g.,* presumptive negative results, serial testing).

(iv) Detailed documentation of analytical studies, including those demonstrating the limit of detection, inclusivity (including relevant variants), cross-reactivity, microbial interference, interfering substances, competitive inhibition, specimen stability, within-lab precision, hook effect, carryover, and cross-contamination, as applicable;

(v) Detailed documentation and characterization (*e.g.,* determination of the identity, supplier, purity, and stability) of all critical reagents and protocols for maintaining product integrity throughout its labeled shelf-life, *i.e.,* reagent stability studies. Data and protocols, including acceptance criteria, from a multi-lot reagent stability study must include testing of samples with challenging analyte concentration and must include in-use or open-kit stability, shipping stability, and freeze-thaw stability (as applicable); and

(vi) Risk analysis and documentation demonstrating how risk control measures are implemented to address device system hazards, such as failure modes effects analysis and/or hazard analysis.

(A) This documentation must include a detailed description of a protocol (including all procedures and methods) for the continuous monitoring, identification, and handling of genetic mutations and/or novel isolates or strains (*e.g.,* regular review of published literature and periodic in silico analysis of target sequences to detect possible mismatches). Protocols must include plans to update labeling with additional performance data. All results of this protocol, including any findings, must be documented and must include any additional data analysis that is requested by FDA in response to any performance concerns identified under this section or identified by FDA during routine evaluation. Additionally, if requested by FDA, these evaluations must be submitted to FDA for FDA review within 48 hours of the request and any results that are reasonably interpreted to support the conclusion that novel SARS-CoV-2 strains or isolates impact the stated expected performance of the device must be sent to FDA immediately to the email provided in FDA's request;

(B) This must include detailed documentation that demonstrates the effectiveness of risk control measures and device robustness, including the entire testing procedure from sampling to result interpretation, based on results from the following studies, as applicable per the intended use of the test device: usability studies, user label comprehension, and flex studies;

(vii) For devices with associated software or instrumentation, documentation must include a detailed description of device software, including software applications and hardware-based devices that incorporate software. The detailed description must include documentation of verification, validation, and hazard analysis and risk assessment activities, including an assessment of the impact of threats and vulnerabilities on device functionality and end users and patients as part of cybersecurity review; and

(viii) For devices intended for the detection of SARS-CoV-2 for which an FDA recommended reference material and/or test panel is available, the performance results of an analytical study testing the FDA recommended reference material. Detailed documentation must be kept of that study and its results, including the study protocol, study report for the proposed intended use, testing results, and results of all statistical analyses.

(7) If one of the actions listed in section 564(b)(1)(A) through (D) of the Federal Food, Drug, and Cosmetic Act occurs with respect to one or more of the analytes claimed in the intended use, or if the Secretary of Health and Human Services (HHS) determines, under section 319(a) of the Public Health Service Act, that a disease or disorder presents a public health emergency, or that a public health emergency otherwise exists, with respect to SARS-CoV-2:

(i) Within 30 days from the date that FDA notifies manufacturers that characterized samples are available for test evaluation, the manufacturer must have testing performed on the device with those samples in accordance with a standardized protocol considered and determined by FDA to be acceptable and appropriate; and

(ii) Within 60 days from the date that FDA notifies manufacturers that characterized samples are available for test evaluation and continuing until 3 years from that date, the results of the emergency analytical reactivity testing, including the detailed information for the samples tested as described in the certificate of authentication, must be included in a tabular format on the hyperlink the manufacturer's public website as described in paragraph (b)(5) of this section.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–14985 Filed 7–23–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket No. FDA–2026–N–7627]

Medical Devices; General Hospital and Personal Use Devices; Classification of the Diabetes Digital Behavioral Therapeutic Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the diabetes digital behavioral therapeutic device into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for classification of the diabetes digital behavioral therapeutic device. We are taking this action because we have determined that classifying the device into class II will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective July 24, 2026. The classification was applicable on July 7, 2023.

FOR FURTHER INFORMATION CONTACT: Joshua Balsam, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3520, Silver Spring, MD 20993–0002, 240–402–6521, *Joshua.Balsam@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the diabetes digital behavioral therapeutic device into class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness of the device. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified into, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (see also part 860, subpart D (21 CFR part 860, subpart D)). Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo classification process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a premarket notification (510(k)) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining ''substantial equivalence''). Instead, sponsors can use the less burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On September 21, 2022, FDA received Better Therapeutics' request for De Novo classification of the BT–001 device. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness of the device, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see section 513(a)(1)(B) of the FD&C Act). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on July 7, 2023, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 880.5735.[1] We have named the generic type of device ''diabetes digital behavioral therapeutic device,'' and it is identified as 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.

FDA has identified the risks to health associated with this type of device and the measures required to mitigate these risks in table 1.

[1] FDA notes that the ''ACTION'' caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR DIABETES DIGITAL BEHAVIORAL THERAPEUTIC DEVICES

Identified 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.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness of the device. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this final order.

At the time of classification, diabetes digital behavioral therapeutic devices are for prescription use only. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met.

Under the FD&C Act, submission of a premarket notification under section 510(k) is required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt under section 510(m) of the FD&C Act. At this time FDA has not made this determination for diabetes digital behavioral therapeutic devices. This device is therefore subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not normally have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 regarding quality management system regulation have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801 regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 880

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 880 is amended as follows:

PART 880–GENERAL HOSPITAL AND PERSONAL USE DEVICES

■ 1. The authority citation for part 880 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 880.5735 to subpart F to read as follows:

§ 880.5735 Diabetes digital behavioral therapeutic device.

(a) *Identification.* 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.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(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.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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