December 15, 2023

Fitbit LLC
Nathan Austin
Regulatory Technical Program Manager
199 Fremont Street, 14th Floor
San Francisco, California 94105

Re: DEN230050
Trade/Device Name: Body Temperature Software (BTS)
Regulation Number: 21 CFR 880.2915
Regulation Name: Body temperature sensing software
Regulatory Class: Class II
Product Code: QZA
Dated: July 14, 2023
Received: July 17, 2023

Dear Nathan Austin:

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 Body Temperature Software (BTS), an over-the-counter device under 21 CFR Part 801 Subpart C with the following indications for use:

> The Body Temperature Software (BTS) App is a software-only mobile medical application intended for over-the-counter (OTC) use with compatible mobile computing platforms that includes a general purpose infrared sensor for the intermittent determination of human body temperature on people of all ages.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Body Temperature Software (BTS), and substantially equivalent devices of this generic type, into Class II under the generic name body temperature sensing software.

FDA identifies this generic type of device as:

> **Body temperature sensing software**. Body temperature sensing software is a software device used for the determination of human body temperature by means of analyzing input sensor data.

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 July 17, 2023, FDA received your De Novo requesting classification of the Body Temperature Software (BTS). The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Body Temperature Software (BTS) 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 Body Temperature Software (BTS) 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:

Risk to Health	**Mitigation Measures**
Inaccurate device output leading to patient receiving incomplete or delayed treatment/diagnosis	Clinical performance testing Non-clinical performance testing Software verification, validation, and hazard analysis Labeling
Poor signal quality resulting in failure to detect elevated body temperature	Non-clinical performance testing Software verification, validation, and hazard analysis Labeling

In combination with the general controls of the FD&C Act, the body temperature sensing software is subject to the following special controls:

(1) For devices where the output temperature is calculated by adjusting the signal from the input sensor, clinical performance testing must demonstrate the accuracy of the device under anticipated conditions of use.

(2) Non-clinical performance testing must demonstrate the ability of the device to detect adequate signal quality under anticipated conditions of use. Testing must evaluate:
   (i) The laboratory accuracy of the device across the intended output range under the intended operating conditions; and
   (ii) The impact of confounding factors on device accuracy.

(3) Software verification, validation, and hazard analysis must be performed. Documentation must include a characterization of the technical specifications of the software, including the application algorithm and its inputs and outputs.

(4) Labeling must include:
  (i) Compatible hardware platform(s) and operating system requirements;
  (ii) Situations in which the device may not operate at an expected performance level;
  (iii) A summary of the clinical performance testing conducted with the device, including a description of the reference body site;
  (iv) Established device performance specifications; and
  (v) Information on interpretation of results.

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 body temperature sensing software 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 Kyran Gibson at Kyran.Gibson@fda.hhs.gov.

Sincerely,

Kellie B. Kelm -S

for
Courtney H. Lias, Ph.D.
Director
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health