February 13, 2025

Fitbit LLC
Nathan Austin
Lead Regulatory Affairs Technical Program Manager
215 Fremont St
San Francisco, California 94105

Re: K243778
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: December 4, 2024
Received: December 9, 2024

Dear Nathan Austin:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Porsche Bennett
For David Wolloscheck Ph.D.
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices, and
Human Factors
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243778

Device Name
Body Temperature Software (BTS)

Indications for Use *(Describe)*
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.

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.

K243778- 510k Summary

This Premarket Notification is submitted by:

Fitbit, LLC.
215 Fremont Street,
San Francisco, CA 94105

Contact Information:

Contact Person: Nathan Austin
Phone: (650) 447-9336
Email: nathanaustin@google.com
Date Prepared: February 13, 2025

Device Trade Name: Body Temperature Software (BTS)

Subject Device Information	
Device Classification Name	Body temperature sensing software
Review Panel	General Hospital
Product Code & Regulation Number	QZA - 21 CFR 880.2915
Regulatory Class	Class II
510k Number	K243778

Predicate Device:

The legally marketed predicate for the subject device is detailed in the table below.

Predicate Device Trade Name	**De Novo**	**Product Code**	**Manufacturer**
Body Temperature Software (BTS)	DEN230050	QZA	Fitbit LLC

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.

Device Description:

The Body Temperature Software ("BTS") mobile application ("App"), is a Software as a Medical Device (SaMD) that leverages an infrared sensor from qualified compatible general computing platforms (i.e. Google Pixel Smartphone) to provide on-demand body temperature measurements. The BTS App is based on well understood infrared measurement technology. The app leverages consumer general purpose computing platforms to collect the inputs for measurement.

The BTS App is intended to be operated by users above 18 years of age and can be used to measure body temperature for themselves or other individuals. To collect the input temperature data, the user is guided to conduct a non-contact forehead sweep starting at the center of the forehead and ending at the temple, thereby passing over the temporal artery, which corresponds to the highest temperature point on the forehead. This temperature data is then used as an input into the BTS App to convert the measured skin temperature data into a body temperature value. Before and during this measurement process, the BTS App performs a series of signal quality checks to ensure the validity of the temperature data collected. Additionally, to aid users with the interpretation of their measurements, the BTS App also has the option to present users with a color-coded temperature guide to indicate if the measurement falls within normal limits or indicative of an elevated state based on well-recognized body temperature ranges for the specified age of the individual being measured.

The BTS App collects the temporal artery temperature, which is processed using a polynomial function to approximate a rectal temperature. The following are the key performance specifications for the BTS App:

- Human Body Temperature Measurement Range: 94.1°F-109.4°F (34.5°C-43°C)
- Laboratory Accuracy (Max): ±0.5°F (±0.3°C)

Operating Ambient Temperature:

- Temperature: 59.0°F-95°F (15°C-35°C)
- Humidity: Humidity Per ASTM E1965-98, up to 95% non-condensing
- Display Resolution: 0.1°C / 0.1°F
- Temperature Scales: Degrees °C / °F
- Storage Conditions (temperature/humidity): -20°C – 40°C (-4°F – 113°F); Humidity up to 95% non-condensing
- Display Modes: Displayed temperature is the temperature of the temporal artery plus a mathematical adjustment to approximate rectal temperature.

The changes subject to this special 510k are the pre-measurement checks and values that are replaced by binary flags to ensure a body temperature measurement is only enabled when the appropriate conditions are met. These flags are:

1. Sensor too warm flag
2. Sensor too cold flag
3. Difference too high flag
4. Skin too warm flag
5. Skin too cold flag

Additionally, the range for the sensor too warm/too cold flag is hardware dependent and no longer a set value.

Comparison of Technological Characteristics:

A summary of substantial equivalence between the subject device and predicate device included in the scope of this Special 510(k) is included in the table below.

Table 1: Summary of Substantial Equivalence

	Subject Device **Body Temperature Software**	**Predicate Device** **Body Temperature Software (DEN230050)**	**Equivalence Discussion**
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.	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.	Same
Intended User	The BTS App is intended to be operated by users above 18 years of age.	The BTS App is intended to be operated by users above 18 years of age.	Same
Device Classification	Class II	Class II	Same
FDA Product Code and Regulatory Classification	QZA - 21 CFR 880.2915 Body temperature sensing software	QZA - 21 CFR 880.2915 Body temperature sensing software	Same
Patient Population	General population excluding premature/preterm infants	General population excluding premature/preterm infants	Same
Prescription	OTC	OTC	Same

or OTC			
Anatomical Site	Forehead using a compatible consumer smartphone with IR sensors.	Forehead using a compatible consumer smartphone with IR sensors.	Same
Use Environment	Home/General Use	Home/General Use	Same
Compatible devices	Pixel 8 Pro and other consumer Pixel smartphone devices deemed compatible with Android 14 operating system release or higher	Pixel 8 Pro with Android 14 operating system release or higher	Different The BTS App is deemed compatible with additional hardware platforms that meet the pre-specified requirements. This addition is to include additional consumer Pixel smartphones as compatible devices and does not raise new questions of safety and effectiveness.
Inputs to BTS	1. Range flag and IR sensor check 2. A temperature signal that qualified smartphone devices generate. a. The Sensor Ambient Temperature is set to Hardware specific ranges. b. Skin too warm/cold checks are binary flags. c. Window temperature difference too high check is a binary flag.	1. Range flag and IR sensor check 2. A temperature signal that qualified smartphone devices generate. a. The Sensor Ambient Temperature parameter is set at 15°C to 35°C	Different The subject device uses binary flags to check for suitable pre-measurement phone hardware conditions. These functions occur outside the SaMD and are maintained in a hardware specification table. The Sensor Ambient Temperature is set to Hardware

			specific ranges with the subject device instead of a defined range. Validated laboratory accuracy testing for the sensor ambient temperature range supports the change not raising new questions of safety and effectiveness. The skin too warm/cold and the difference too high flags have been modified to be binary flags instead of specified ranges. This difference is evaluated using software verification and does not raise new questions of safety and effectiveness.
Principle of operation	A user's temperature is measured when a forehead measurement sweep is performed with the infrared sensor and the signal input data is provided by the platform to the BTS App algorithm. The BTS App performs a series of checks prior to launching, during the sweep and during the processing of the signal to ensure that the temperature data collected is valid for processing. Using this valid collected	A user's temperature is measured when a forehead measurement sweep is performed with the infrared sensor and the signal input data is provided by the platform to the BTS App algorithm. The BTS App performs a series of checks prior to launching, during the sweep and during the processing of the signal to ensure that the temperature data collected is valid for processing. Using this valid collected data, the BTS App algorithm	Same

	data, the BTS App algorithm processes the sensor data collected during the sweep and determines the body temperature. The displayed temperature is that of the temporal artery which is processed using a polynomial function to approximate a rectal temperature.	processes the sensor data collected during the sweep and determines the body temperature. The displayed temperature is that of the temporal artery which is processed using a polynomial function to approximate a rectal temperature.	
Specifications			
Human body temperature Measurement Range (Min/Max Accuracy)	94.1°F-109.4°F (34.5°C-43.0°C)	94.1°F-109.4°F (34.5°C-43.0°C)	Same
Laboratory Accuracy (Max)	±0.5°F (±0.3°C)	±0.5°F (±0.3°C)	Same
Measurement Site	Temporal Artery	Temporal Artery	Same
Reference Body Site	Rectal	Rectal	Same
Human body temperature Measurement Range (Min/Max Accuracy)	94.1°F-109.4°F (34.5°C-43.0°C)	94.1°F-109.4°F (34.5°C-43.0°C)	Same
Operating Ambient Ranges			
Temperature	59.0°F-95.0°F (15.0°C-35.0°C)	59.0°F-95.0°F (15.0°C-35.0°C)	Same
Display Resolution	0.1°F/0.1°C	0.1°F/0.1°C	Same

Temperature Scales	Degrees °F/°C	Degrees °F/°C	Same

Summary of Non-Clinical Testing:

The intended use of the subject device and predicate are identical, and their technological characteristics are similar. The subject device is a modification of the predicate device and utilizes the same design and operating principles. The device modifications have been verified and do not raise any new or different questions of safety and effectiveness.

The device demonstrated a laboratory accuracy of ±0.3°C per ISO 80601-2-56. Risk management was conducted in accordance with ISO 14971.

The following testing was conducted to demonstrate that the modifications to the subject device are as safe and effective as the predicate.

- Validation Testing

Results of these tests demonstrate that the functionality, safety, and effectiveness of the subject device are adequate for their intended use, indications for use and support a determination of substantial equivalence.

Summary of Clinical Testing:

Clinical testing was not required for this Special 510(k).

Conclusion:

The proposed modifications to the subject device do not alter the indications for use, intended use, user interface or its core algorithm. There are no differences in the indications for use and intended use between the subject and predicate devices.

One of the technological differences is that pre-measurement checks related to ‘Sensor Ambient Temperature’, ‘Skin temperature’, and ‘Sensor Window Temperature’ values are replaced by binary flags that function similarly to proximity flag check in that a body temperature measurement is only enabled when the appropriate conditions are met. Additionally, the Sensor Ambient Temperature range is being set to hardware specific range instead of a predefined range.

Laboratory accuracy testing and software verification show that the modifications to the software do not raise new or different questions of safety and effectiveness and the device demonstrates substantial equivalence to the predicate device.

The subject device is substantially equivalent to the predicate device, Body Temperature Software (BTS), DEN230050.