March 6, 2025

Omron Healthcare, Inc.
% Kit Cariquitan
Executive Director, Regulatory Affairs
Veranex, Inc.
5420 Wade Park Blvd, Suite 204
Raleigh, North Carolina 27607

Re: DEN230076
Trade/Device Name: Omron Blood Pressure Monitor with Atrial Fibrillation (AFib) Detection Feature (BP7460 (HEM-7371T1-AZ)); Omron Blood Pressure Monitor with Atrial Fibrillation (AFib) Detection Feature (BP5460 (HEM-7372T1-AZAZ))
Regulation Number: 21 CFR 870.1135
Regulation Name: Oscillometric-based, over-the-counter, atrial fibrillation notification feature
Regulatory Class: Class II
Product Code: QXY
Dated: November 9, 2023
Received: November 13, 2023

Dear Kit Cariquitan:

This letter corrects our previous classification order, dated October 8, 2024, to correct the indications for use.

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 Omron Blood Pressure Monitor with Atrial Fibrillation (AFib) Detection Feature (BP7460 (HEM-7371T1-AZ)); Omron Blood Pressure Monitor with Atrial Fibrillation (AFib) Detection Feature (BP5460 (HEM-7372T1-AZAZ)), an over-the-counter device under 21 CFR Part 801 Subpart C with the following indications for use:

> The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population. The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.
>
> The device includes the Atrial Fibrillation Detection Feature. The feature analyzes pulse pressure wave data captured during the user's blood pressure measurement to identify episodes of atrial fibrillation (AFib) and provides a notification on the display screen to the user. This feature is intended to be used for home screening for the possibility of AFib.

The Atrial Fibrillation Detection Feature is not intended to provide a notification on every episode of AFib and the absence of detection is not intended to indicate the absence of atrial fibrillation. The feature is not intended to replace traditional methods of diagnosis or treatment or to be used in the management of patients with AFib.

The device is intended for over-the-counter (OTC) use in the home environment. The device is intended for use in adults (22 years or older); it has not been tested for and is not intended for use in pregnant women or people with implanted pacemakers or defibrillators.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Omron Blood Pressure Monitor with Atrial Fibrillation (AFib) Detection Feature (BP7460 (HEM-7371T1-AZ)); Omron Blood Pressure Monitor with Atrial Fibrillation (AFib) Detection Feature (BP5460 (HEM-7372T1-AZAZ)), and substantially equivalent devices of this generic type, into Class II under the generic name oscillometric-based, over-the-counter, atrial fibrillation notification feature.

FDA identifies this generic type of device as:

Oscillometric-based, over-the-counter, atrial fibrillation notification feature. An oscillometric-based, over-the-counter, atrial fibrillation notification feature is a software algorithm for analysis of signals from an oscillometric, non-invasive blood pressure measurement system to screen for possible atrial fibrillation in the device user.

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 November 13, 2023, FDA received your De Novo requesting classification of the Omron Blood Pressure Monitor with Atrial Fibrillation (AFib) Detection Feature (BP7460 (HEM-7371T1-AZ)); Omron Blood Pressure Monitor with Atrial Fibrillation (AFib) Detection Feature (BP5460 (HEM-7372T1-AZAZ)). The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Omron Blood Pressure Monitor with Atrial Fibrillation (AFib) Detection Feature (BP7460 (HEM-7371T1-AZ)); Omron Blood Pressure Monitor with Atrial Fibrillation (AFib) Detection Feature (BP5460 (HEM-7372T1-AZAZ)) 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 Omron Blood Pressure Monitor with Atrial Fibrillation (AFib) Detection Feature (BP7460 (HEM-7371T1-AZ)); Omron Blood Pressure Monitor with Atrial Fibrillation (AFib) Detection Feature

(BP5460 (HEM-7372T1-AZAZ)) 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**
False positive resulting in unnecessary medical intervention	Clinical performance testing Non-clinical performance testing Software verification, validation, and hazard analysis Human factors testing Labeling
False negative resulting in failure to detect atrial fibrillation and delayed treatment.	Clinical performance testing Non-clinical performance testing Human factors testing Software verification, validation, and hazard analysis Labeling
Misinterpretation and/or over-reliance on device output, leading to failure to seek treatment despite symptoms, or inappropriate treatment changes.	Human factors testing Software verification, validation, and hazard analysis Labeling

In combination with the general controls of the FD&C Act, the oscillometric-based, over-the-counter, atrial fibrillation notification feature is subject to the following special controls:

(1) Clinical performance testing must compare the device algorithm performance against readings from patients with and without AFib that have been clinically adjudicated and evaluate the sensitivity and specificity of the output measurement. Justification for the clinical adjudication procedures to determine ground truth must be provided.
(2) Non-clinical performance testing of the algorithm must include:
    (i) Evaluation and qualification of interoperability with the oscillometric hardware components; and
    (ii) Validation of the device to detect adequate motion/noise artifacts during measurement.
(3) Software verification, validation, and hazard analysis must be performed. Documentation must include a characterization of the technical specifications of the software, including the diagnostic algorithm and its inputs and outputs.
(4) Human factors and usability testing must demonstrate the following:
    (i) The user can correctly use the device based solely on reading the device labeling;
    (ii) The user can correctly interpret the device output and understand when to seek medical care; and
    (iii) The user understands situations during which the device should not be used.
(5) Labeling must include:

(i) A description of what the device measures and outputs to the user;
(ii) Situations in which the device may not operate at an expected performance level and when its use may pose risks to the user;
(iii) A summary of the clinical performance testing conducted with the device, including user demographics;
(iv) Guidance on interpretation of any measurements, detection results, and error messages; and
(v) Hardware platform requirements.

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 oscillometric-based, over-the-counter, atrial fibrillation notification feature 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 Sean Pereira at sean.pereira@fda.hhs.gov.

Sincerely,

Misti L. Malone -S

for

Bram Zuckerman, M.D.
Director
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health