



**U.S. FOOD & DRUG
ADMINISTRATION**

September 12, 2025

Apple Inc.
Bonnie Wu
Regulatory Affairs Lead
One Apple Park Way
Cupertino, California 95014

Re: K250507

Trade/Device Name: Hypertension Notification Feature (HTNF)
Regulation Number: 21 CFR 870.2380
Regulation Name: Cardiovascular Machine Learning-Based Notification Software
Regulatory Class: Class II
Product Code: SFR

Dear Bonnie Wu:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change for your device cleared on September 11, 2025. Specifically, FDA is updating this substantial equivalence (SE) letter as an administrative correction to include the correct version of the 510(k) Summary for K250507. FDA is also updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact LCDR Stephen Browning, OHT2: Office of Cardiovascular Devices, 240-402-5241, stephen.browning@fda.hhs.gov.

Sincerely,

Stephen C. Browning -S

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health



September 11, 2025

Apple Inc.
Bonnie Wu
Regulatory Affairs Lead
One Apple Park Way
Cupertino, California 95014

Re: K250507

Trade/Device Name: Hypertension Notification Feature (HTNF)
Regulation Number: 21 CFR 870.2380
Regulation Name: Cardiovascular Machine Learning-Based Notification Software
Regulatory Class: Class II
Product Code: QXO
Dated: February 20, 2025
Received: February 21, 2025

Dear Bonnie Wu:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not

required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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,


Stephen C. Browning -S

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K250507

?

Please provide the device trade name(s).

?

Hypertension Notification Feature (HTNF)

Please provide your Indications for Use below.

The Hypertension Notification Feature (HTNF) is a software-only mobile medical application that analyzes photoplethysmography (PPG) data opportunistically collected by Apple Watch to identify patterns that are suggestive of hypertension and provides a notification to the user.

The feature is intended for over-the-counter (OTC) use by adults age 22 and over who have not been previously diagnosed with hypertension. It is not intended to replace traditional methods of diagnosis, to monitor hypertension treatment effect, or to be used as a method of blood pressure surveillance. It is not intended for use during pregnancy. The absence of a notification does not indicate the absence of hypertension.

Please select the types of uses (select one or both, as applicable).

☐ Prescription Use (Part 21 CFR 801 Subpart D)

☒ Over-The-Counter Use (21 CFR 801 Subpart C)

?

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

1. Submitter

Applicant	Apple Inc. One Apple Park Way Cupertino, CA 95014
Primary Correspondent	Bonnie Wu Regulatory Affairs Lead Phone: (408) 974-0617 Email: bonnie_h_wu@apple.com
Secondary Correspondent	Sam Surette US Regulatory Affairs Manager Phone: (628) 629-4161 Email: ssurette@apple.com
Date Prepared	Feb. 20, 2025

2. Device Names and Classifications

Subject Device:

Name of Device	Hypertension Notification Feature (HTNF)
Classification Name	Cardiovascular Machine Learning-Based Notification Software, 21 CFR 870.2380
Regulatory Class	Class II
Product Code	SFR
510(k) Review Panel	Cardiovascular

Predicate Device:

Predicate Manufacturer	Viz.ai, Inc.
Predicate Trade Name	Viz HCM
Predicate 510(k)	DEN230003

3. Device Description

The Hypertension Notification Feature (HTNF) is an over-the-counter mobile medical application that is intended to analyze data collected from the PPG sensor of the Apple Watch (a general purpose computing platform), over multiple days to surface a notification to users who may have hypertension. The feature is intended for adults who have not been previously diagnosed with hypertension. The feature is not intended for use during pregnancy. The feature is not intended to replace traditional methods of diagnosis, to monitor hypertension treatment effect, or to be used as a method of blood pressure surveillance.

Absence of a notification does not indicate the absence of hypertension. HTNF cannot identify every instance of hypertension. In addition, HTNF will not surface a notification if insufficient data is collected.

HTNF comprises the following features:

- A software feature on the Apple Watch (“Software Feature on Watch”), and
- A pair of software features on the iOS device (“Software Feature on iPhone” and “Software Feature on iPad”)

On the Apple Watch, HTNF uses PPG data and qualification information from the watch platform. The Software Feature on watch incorporates a machine-learning model that gives each qualified PPG signal a score associated with risk of hypertension.

On the iPhone, HTNF incorporates an algorithm that aggregates qualified hypertension risk scores and identifies patterns suggestive of hypertension. If hypertension patterns are identified, the feature surfaces a notification to users that they may have hypertension. The feature includes a user interface (UI) framework to enable user on-boarding and display educational materials and hypertension notification history in the Hypertension Notification room in the Health app.

On the iPad, HTNF provides a data viewing framework to display hypertension notification history in the Hypertension Notification room in Health app.

4. Indications for Use

The Hypertension Notification Feature (HTNF) is a software-only mobile medical application that analyzes photoplethysmography (PPG) data opportunistically collected by Apple Watch to identify patterns that are suggestive of hypertension and provides a notification to the user.

The feature is intended for over-the-counter (OTC) use by adults age 22 and over who have not been previously diagnosed with hypertension. It is not intended to replace traditional methods of diagnosis, to monitor hypertension treatment effect, or to be used as a method of blood pressure surveillance. It is not intended for use during pregnancy. The absence of a notification does not indicate the absence of hypertension.

5. Comparison with the Predicate Device

HTNF and the predicate device (Viz HCM, DEN230003) have the same intended use, technological characteristics, and principles of operation, and the difference in indications does not represent a new intended use. Both the subject and predicate devices are software-only mobile medical applications intended to identify a single condition based on non-invasive

physiological inputs and suggest the likelihood of a cardiovascular disease for further referral or diagnostic follow-up. Both devices are intended as the basis for further testing and are not intended to provide diagnostic quality output.

The subject device contains some differences in indications for use:

- HTNF is indicated for identifying possible hypertension. Viz HCM is indicated for possible hypertrophic cardiomyopathy (HCM).
- HTNF is indicated for adult users (22+ years) who are not diagnosed with hypertension nor is it indicated for use during pregnancy. Viz HCM is indicated for adult users (18+ years) who do not have implanted pacemakers.
- HTNF is intended to be used by lay users as an over-the-counter (OTC) device. Conversely, Viz HCM is intended to be used as a prescription device by clinicians in a hospital setting.

Additionally, the subject device contains some differences in technological characteristics:

- The subject device is a passive, opportunistic device that analyzes PPG signal collected over multiple days and surfaces notifications only when patterns of hypertension are identified. Viz HCM analyzes 12-Lead ECG signal and provides on-demand analysis.

The differences in indications and technological characteristics described above do not raise new questions of safety or effectiveness. The differences can properly be evaluated through the special controls established in 21 CFR 870.2380. The subject device has been appropriately verified and validated through non-clinical and clinical testing to ensure that the device is substantially equivalent to the predicate. A complete comparison of the subject and predicate device can be found in **Table 1** below.

Table 1. Subject Device and Predicate Device Comparison Table

Item	Subject Device	Predicate Device
	HTNF	Viz HCM
Device Name	Hypertension Notification Feature	Viz HCM
Manufacturer	Apple Inc.	Viz.ai, Inc.
Product Code	SFR	QXO
Regulation Name	Cardiovascular Machine Learning-Based Notification Software	Cardiovascular Machine Learning-Based Notification Software
OTC/Prescription	OTC	Prescription
Intended Use	The Hypertension Notification Feature (HTNF) is a machine-learning-based notification software that employs machine learning techniques to identify possible hypertension for further diagnostic follow-up. The	Viz HCM is a cardiovascular machine-learning-based notification software employs machine learning techniques to detecting signs associated with hypertrophic cardiomyopathy (HCM). Viz HCM

Item	Subject Device	Predicate Device
	HTNF	Viz HCM
	software identifies patterns that are suggestive of hypertension based on photoplethysmography (PPG) data opportunistically collected by Apple Watch. It is intended as the basis for further evaluation and is not intended to provide a diagnosis of hypertension.	analyzes recordings of 12-lead ECG and identifies patients for further HCM follow-up and does not replace the current standard of care methods for diagnosis of HCM.
Indications for Use	The Hypertension Notification Feature (HTNF) is a software-only mobile medical application that analyzes photoplethysmography (PPG) data opportunistically collected by Apple Watch to identify patterns that are suggestive of hypertension and provides a notification to the user. The feature is intended for over-the-counter (OTC) use by adults age 22 and over who have not been previously diagnosed with hypertension. It is not intended to replace traditional methods of diagnosis, to monitor hypertension treatment effect, or to be used as a method of blood pressure surveillance. It is not intended for use during pregnancy. The absence of a notification does not indicate the absence of hypertension.	Viz HCM is intended to be used in parallel to the standard of care to analyze recordings of 12-lead ECG made on compatible ECG devices. Viz HCM is capable of analyzing the ECG, detecting signs associated with hypertrophic cardiomyopathy (HCM), and allowing the user to view the ECG and analysis results. Viz HCM is indicated for use on 12-lead ECG recordings collected from patients 18 years of age or older. Viz HCM is not intended for use on patients with implanted pacemakers. Viz HCM is limited to analysis of ECG data and should not be used in-lieu of full patient evaluation or relied upon to make or confirm diagnosis. Viz HCM identifies patients for further HCM follow-up and does not replace the current standard of care methods for diagnosis of HCM. The results of the device are not intended to rule-out HCM follow-up.
Principle of Operation	HTNF analyzes PPG data collected by the sensor on the Apple Watch platform and identifies patterns suggestive of hypertension. HTNF surfaces a notification to user that they may have hypertension.	Viz HCM analyzes 12-lead ECG recordings collected from compatible ECG devices and identifies signs associated with hypertrophic cardiomyopathy. The software allows users to view the ECG and analysis results.

Item	Subject Device	Predicate Device
	HTNF	Viz HCM
Target Population	Adults without previous HTN diagnosis. Not intended for pregnant users	Adult patients. Not intended for patients with implanted pacemakers.
Intended User	Lay user	Clinician
Overall Device Design	A software-only device, and uses a machine learning-based algorithm to analyze input sensor signals from a general purpose computing platform and provide an assessment for the presence of hypertension. Assessments are based on sensor data opportunistically collected over 30-day periods. The device is intended to provide passive and opportunistic detection of hypertension, such that after initial enrollment no user interaction is required for the device to perform as intended.	A software-only device, and uses a machine learning-based algorithm to analyze input signals from a ECG device and provide an assessment for the presence of HCM. Assessments are conducted on demand in clinic or hospital setting, such that the findings can be provided to health care professionals for further analysis.
Use Environment	At home use	In clinic or hospital use
Device Components	Software only	Software only
Device Input	PPG data from compatible Apple Watch platforms	12-Lead ECG from compatibles ECG devices
Device Output	A notification that the user may have hypertension	Identified signs associated with HCM and ECG analysis results
Clinical Performance	The performance was demonstrated to be acceptable for identifying potential hypertension within the intended population. Sensitivity: 41.2% (95% CI [37.2, 45.3]) Specificity: 92.3% (95% CI [90.6, 93.7]) PPV (prevalence of 31.4%): 70.9% (95% CI [65.7, 75.7])	Sensitivity: 68.4% (95% CI [62.8, 73.5]) Specificity: 99.1% (95% CI [98.7, 99.4]) PPV (prevalence of 0.002): 13.7% (95% CI [10.1, 19.9])

6. Algorithm Development

HTNF incorporated a machine learning (ML)-based algorithm to identify key PPG patterns that are suggestive of hypertension. The ML-based algorithm comprises of two key models:

- A deep-learning (DL) model developed using a self-supervised learning method based on a large-scale unlabeled data to extract generalizable characteristics of the PPG input signals. The unlabeled data included Apple Watch sensor data collected over 86,000 participants.
- A Linear model trained on top of the DL model to provide specific hypertension classifications (hypertensive vs. non hypertensive). The algorithm development dataset included Apple Watch sensor data and home blood pressure reference measurements collected over 9,800 participants.

For the purposes of ML algorithm development, data collected was pooled and split into four sets: Training, Train Dev, Test Dev, and Test. The model was trained on the Training dataset, with the Train Dev dataset used for model iterations and threshold selections. The model was subsequently evaluated on the Test Dev dataset at significant development milestones throughout the model's development. When development was complete and the model was locked, it was evaluated on the Test dataset as a last test to ensure it had not been over-fit to the training data. This process ensured no subject overlap and matching distributions of age, sex, BMI, and disease severity. The development data included a diverse group of subjects with respect to demographic factors (e.g., age, sex, race, ethnicity, and BMI) that are representative of the intended use population.

7. Summary of Non-Clinical Performance Testing

Extensive non-clinical testing was conducted with passing results supporting a determination of substantial equivalence. Non-clinical testing conducted included the following:

Software Verification and Validation

Software verification and validation was conducted in accordance with Apple's robust Quality Management System and documented to address the recommendations in FDA's 2023 Guidance, "*Content of Premarket Submissions for Device Software Functions*." HTNF was determined to require a Basic Documentation Level. Apple's good software engineering practices, as demonstrated through the submission's documentation, supports a conclusion that HTNF was appropriately designed, verified, and validated.

Cybersecurity

Apple's approach to cybersecurity aligns with FDA's 2023 Guidance, "*Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*." The device also conforms to the cybersecurity requirements identified in Section 524B to the FD&C Act.

Human Factors Validation

HTNF was found to be safe and effective as compared to the predicate for the intended users, uses, and use environments. This conclusion is supported by iterative human factors analyses

and evaluations on the device, resulting design modifications and the analysis of the summative validation testing results as recommended by 2016 FDA Guidance, “*Applying Human Factors and Usability Engineering to Medical Devices*.”

General Purpose Computing Platform Testing

HTNF is a software-only device available on compatible general purpose computing platforms (e.g. Apple Watch); therefore, medical device hardware testing is not applicable. However, as a multiple function device product, the impact of the general purpose computing platform on HTNF was assessed per FDA’s 2020 Guidance, “*Multiple Function Device Products: Policy and Considerations*” and determined to be acceptable. This is consistent with the impact assessment of other Apple medical device features made available on Apple Watch, such as the Irregular Rhythm Notification Feature (K231173), the Atrial Fibrillation History Feature (K213971), and Sleep Apnea Notification Feature (K240929).

8. Summary of Clinical Performance

Clinical Validation

A pivotal clinical validation study was conducted to demonstrate the clinical benefits measured by subject level sensitivity and specificity in identifying hypertension status in the intended population and intended use environment.

The primary objective of the clinical validation was to examine the performance of HTNF in detecting possible hypertension over a 30-day period. Hypertension is established as average systolic blood pressure ≥ 130 mmHg or diastolic blood pressure ≥ 80 mmHg by American Heart Association.

A total of 2,229 subjects without a previous diagnosis of hypertension were enrolled in the clinical study. The subjects were enrolled from diverse demographic groups and representative of the intended use population with a range of blood pressures categorized as non-hypertensive (normal or elevated) or hypertensive (stage 1 and stage 2) in accordance with definitions published in the 2017 American Heart Association Guidelines. All subjects were asked to wear an Apple Watch for 30 days and measured blood pressure using an FDA-cleared home blood pressure monitor as reference. Of the 2,229 enrolled subjects, 1,863 provided at least 15 days of usable data for the primary endpoint analysis.

The clinical study results demonstrated that:

- The feature met all pre-determined primary endpoints. The overall sensitivity and specificity were 41.2% (95% CI [37.2, 45.3]) and 92.3% (95% CI [90.6, 93.7]), respectively.
- The sensitivity for stage 2 hypertension was 53.7% (95% CI [47.7, 59.7]) and the specificity for normotensive was 95.3% (95% CI [93.7, 96.5]).
- Demographic subgroup analyses were conducted using covariate adjusted analysis to correct demographic imbalances. The results are presented as risk ratios in **Table 2** and **Figure 1**, where point estimates and confidence intervals of the ratio of sensitivities and ratio of specificities between categories of the demographic subgroups are reported. The demographic subgroup analyses were pre-specified and adjusted for age, sex, BMI, race, and Blood Pressure. For each evaluated demographic characteristic, the subcategory listed (or listed first, in **Table 1**) serves as the numerator of the risk ratio. For example, a

sensitivity risk ratio of less than 1.0 in the younger age group (<60 years) means this group has a lower covariate-adjusted sensitivity than the older group (≥ 60) years. A specificity risk ratio of greater than 1.0 in the younger age group means this group has a higher covariate-adjusted specificity than the older group. Because a risk ratio of 1.0 indicates equal performance between subcategories, differences were considered nonsignificant if the 95% confidence interval included 1.0.

Table 2. Subgroup Performance - HTNF Clinical Study

Subgroup		Sensitivity Risk Ratio [95% CI]	Specificity Risk Ratio [95% CI]
Age (<60 vs. ≥ 60 years)		0.69 [0.55, 0.85]	1.09 [1.04, 1.15]
Sex (Female vs. Male)		0.93 [0.77, 1.12]	0.97 [0.93, 1.03]
Race	Not White vs. White	0.87 [0.69, 1.10]	1.04 [1.01, 1.07]
	Not Black vs. Black	1.20 [0.93, 1.54]	0.97 [0.93, 1.00]
	Not Asian vs. Asian	1.42 [0.86, 2.35]	1.00 [0.97, 1.04]
Ethnicity (Hispanic vs. Not Hispanic)		1.41 [1.07, 1.88]	1.02 [0.97, 1.06]
BMI (≤ 30 vs. >30 kg/m ²)		0.67 [0.55, 0.81]	1.06 [1.02, 1.11]
Fitzpatrick Skin Tone (I-IV vs. V-VI)		1.11 [0.84, 1.47]	0.98 [0.93, 1.02]

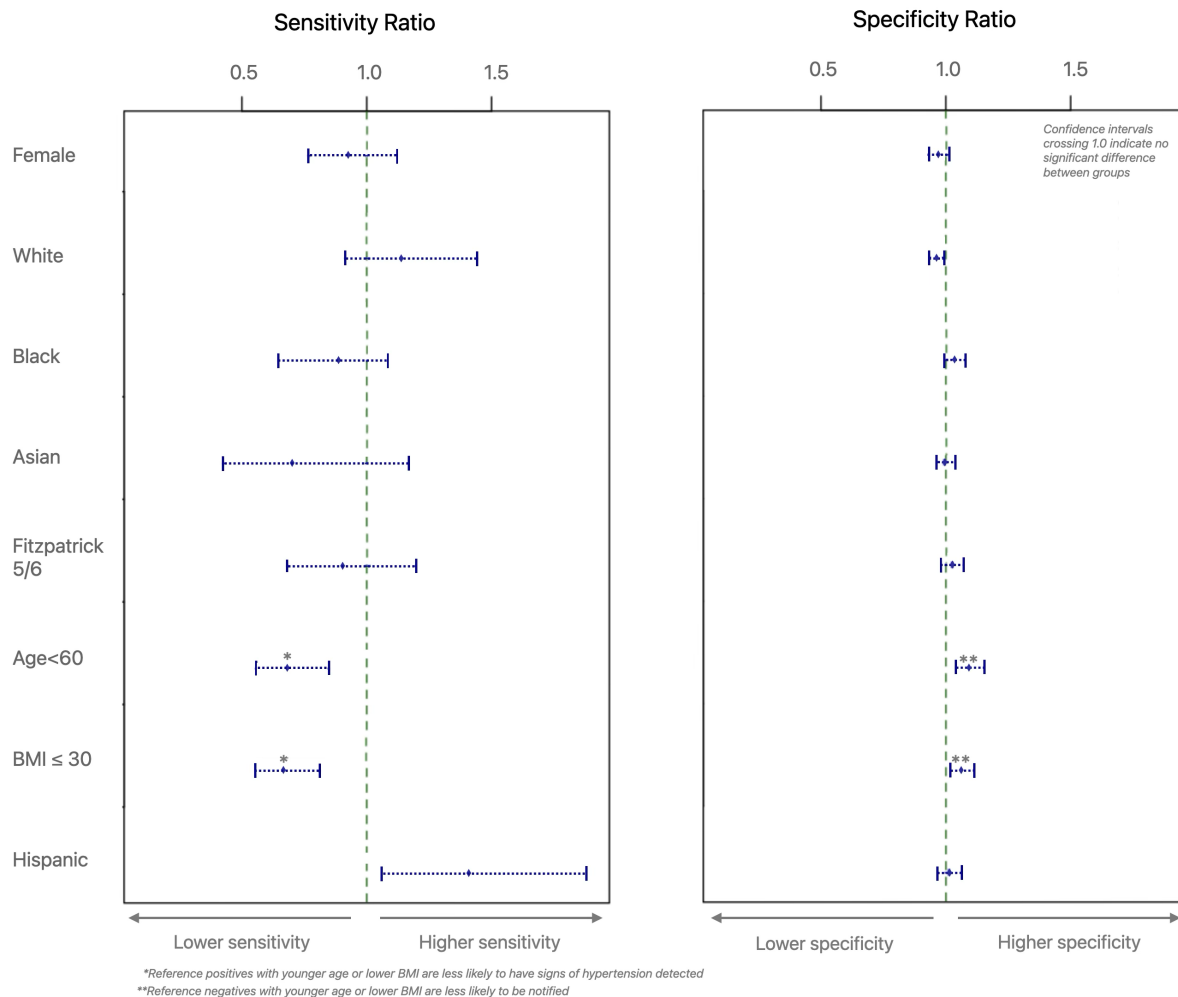


Figure 1 Sub-group Performance Risk Ratio Analysis

- Higher sensitivity and lower specificity were observed in those with older age (age ≥ 60 years) and higher BMI (BMI > 30 kg/m²). The result was deemed clinically acceptable due to the higher risk nature of these subgroups. Importantly, comparisons of sex, race, and skin tone suggested no clinically meaningful difference after covariate adjustment. For example, the Asian subgroup was younger (mean age 43.0 vs. 50.9 years) and had lower BMI (mean BMI 27.7 vs. 30.9 kg/m²) compared to non-Asian participants. After covariate adjustment Asian performance characteristics were on par with non-Asian participants.

Longitudinal Performance Evaluation

A study was conducted over two years to evaluate long-term performance of HTNF, analyzing patient data containing six discrete non-overlapping 30-day evaluation windows. After adjusting for demographic characteristic imbalances between this study and the pivotal clinical study to facilitate comparisons, the results showed the long-term specificity for non-hypertensives (N=187) remained high at 86.4% (95% CI [80.2%, 92.5%]), as did the specificity for the subset of non-hypertensives with normal blood pressure (N=121) which was 92.5%

(95% CI [86.8%, 98.3%]). Importantly, as shown in **Figure 2**, the majority of participants without hypertension who received a notification did so in the first month, and the number of new notifications within this group tended to decrease month-over-month. This pattern held for non-hypertensives overall and those with normal blood pressure.

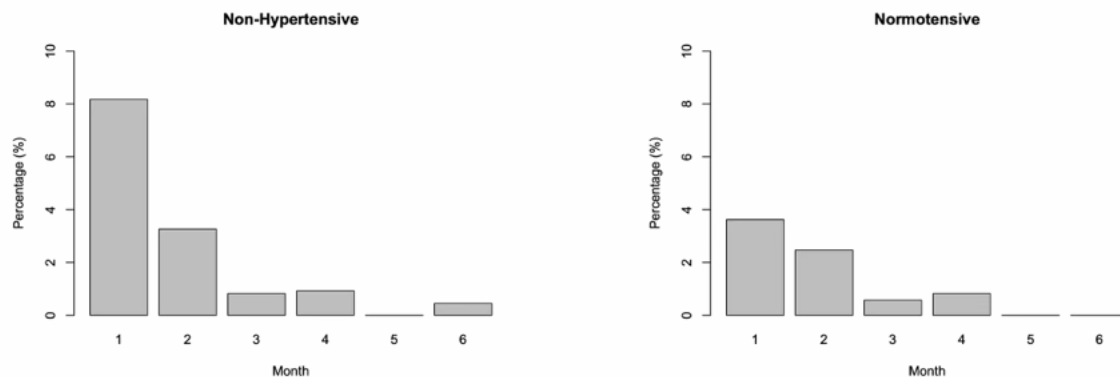


Figure 2 Adjusted Percentage of New False Positives Per Month Over 6 Months

Performance Summary

HTNF performance exceeded the pre-specified performance goals for sensitivity and specificity. The primary and secondary endpoint analyses confirmed that the Hypertension Notification Feature algorithm provided appropriate specificity and sensitivity in surfacing notifications for possible hypertension.

9. Predetermined Change Control Plan (PCCP)

This HTNF submission contains a Predetermined Change Control Plan (PCCP), which complies with Section 3308 of the Food and Drug Omnibus Reform Act (FDORA) of 2022, enacted on December 29, 2022. The PCCP does not include provisions for implementation of adaptive algorithms that will continuously learn in the field. All algorithm modifications will be trained, tuned, and locked prior to release of the software to the field. A procedure has also been established for updating the Instructions for Use in order to inform users about the changes implemented under this FDA-authorized PCCP, including a summary of the changes, a characterization of algorithm performance, and the availability and compatibility of the feature.

The PCCP specifies possible modifications to HTNF, as well as verification and validation activities in place to implement the changes in a controlled manner such that the modified device remains as safe and effective as the predicate device. The PCCP includes a list of feature changes defining the specific regions of potential modifications (see **Table 3**). The modification protocol incorporates impact assessment considerations and specifies requirements for data management, including data sources, collection, storage, and sequestration, as well as documentation and data re-use practices. A total of two test methods (see **Table 4**) are defined in the PCCP to establish substantial equivalence relative to the predicate device, including sample size determination, demographic requirements, analysis methods, and acceptance criteria. Verification and Validation activities will be conducted in accordance to the test methods to compare the performance of the modified HTNF to the

initial release to ensure that the feature remains safe and effective across the intended use population.

The PCCP specifies a framework for instructions for use updates in order to inform users about the modifications implemented. The instructions for use updates include the following elements:

- A description of the modification implemented,
- A summary of algorithm development deployed to implement the modification, such as relevant data and practices (e.g., training, tuning, and test data, algorithm inputs and outputs),
- A description of the specific validation methods and requirements used to evaluate the performance of the modification

Table 3. Proposed Modifications to HTNF under the PCCP

Feature Component	Modification
Modifications to Machine Learning Modules	• Revise PPG signal input characteristics • Incorporate demographic data input types for the ML model • Revise how DL model processes PPG channel inputs
	• Implement quantization • Retraining • Modify basic hyper-parameters
Modifications to Hypertension Notification Logic	• Modify logic for surfacing a notification • Reduce the minimum data required for notification

Table 4: Test Methods and Data Collection Approaches

Evaluation Test Method	Data Collection Approach	Comparative Analysis
Single Watch Test Method	Single Watch data collection: The study subjects will wear one compatible Apple Watch on the subject's preferred wrist and undergo daily data collection.	Establish non-inferiority of HTNF updated performance compared to initial release
Dual Watch Test Method	Dual Watch data collection: The study subjects will simultaneously wear two Apple Watches, one on each wrist, and undergo daily data collection. The subject will swap the watches on	Establish non-inferiority of HTNF updated performance with updated platform compared to initial release

Evaluation Test Method	Data Collection Approach	Comparative Analysis
	day 15 of the 30-day study period, to minimize physiological or behavioral biases from wrist wear. The wrist assignment for each of the two watches will be randomized at the start of the study.	

10. Conclusion

HTNF is substantially equivalent to the Viz HCM as they are identical with respect to intended use and there are no differences in technological or performance characteristics that raise new questions of safety and effectiveness.