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