Review Summary

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March 9, 2026

Pharmaceuticals and Medical Devices Agency

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The following are the summary of the review of the following medical device submitted for marketing approval conducted by the Pharmaceuticals and Medical Devices Agency (PMDA).

Classification	:	Program 1, Diagnostic Program
Term name	:	Software for analysis of home use pulse wave information
Brand name	:	Apple's Hypertension Notification Feature
Applicant	:	Apple Inc.
Date of application	:	April 8, 2025
Date of approval	:	November 5, 2025
Application classification	:	☐New medical device ☒Improved medical device (with clinical data)
		☐Improved medical device (without clinical data)
New approval / partial change	:	☒New Approval ☐Partial Change
Review category	:	☐Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry
		☐Cardiopulmonary Circulation
		☐Dentistry and Oral Medicine
		☐Gastroenterology, Genitourinary, and Reproductive Medicine
		☐Ophthalmology and Otorhinolaryngology
		☐Orthopedic and Plastic Surgery
		☐Robotics, IoT, and other devices (not classified as other categories)
		☒Program D1
		☐Program D2
Items warranting special mention	:	☐Designated as medical devices with high medical need
		☐Designated as specific-usage medical device
		☐Application in accordance with conditional early approval system for medical devices (Type 1)
		☐Application in accordance with conditional early approval system for

medical devices (Type 2: "Physical operation of items' extrapolative and inclusive approval" (Phoenix))

☐Application in accordance with the notification on pre- and post-market rebalancing (☐1st step ☐2nd step)

☐Application in accordance with "Improvement design within approval for timely evaluation and notice" (IDATEN)

☐Designated as orphan medical device

☐Application in accordance with the 0929 notification

☐Other (   )

Expert Discussion   :   ☒Yes ☐No

1. Submitted data

(1) **Background of the development**

This product is a software for analysis of home use pulse wave information used to analyze data obtained by photoplethysmography, detect patterns suggestive of hypertension, and notify the users. It is intended for use by users aged 22 years and older who have never been diagnosed with hypertension. The difference with existing products is the detection and notification of the possibility of hypertension and aim to encourage visits to medical institutions. Expert discussion was held to ask opinions on the details of information provided to users and healthcare professionals after marketing.

(2) **Non-clinical Data**

The following nonclinical data were submitted.

- Software Lifecycle Process, Usability Engineering and Cybersecurity Evaluated for conformity to IEC 62304:2015, IEC 62366-1:2020 and IEC 81001-5-1:2021, respectively
- Documents evaluating the proper operation of each function

(3) **Clinical Data**

The results of the Cardiac Risk Factors study conducted in the United States were submitted. The outline of the Cardiac Risk Factor study is as follows (the clinical results section of the package insert is cited, and table numbers are modified as necessary).

A prospective, decentralized, nonsignificant risk study was conducted in the United States to evaluate the estimated performance of Apple's Hypertension Notification Feature in diagnosing hypertension in 2,229 patients with no history of hypertension diagnosis.

Subjects represented the population intended to use this product, having blood pressure within the classification range of non-hypertension (normotensive or elevated) or hypertension (stage 1 and stage 2) as defined in the 2017 AHA Guidelines for Hypertension. Subjects wore an Apple Watch for 30 days, and measured baseline blood pressure data every day, twice in the morning and twice at night, using an Omron HCR-7608T2 sphygmomanometer.

Table 1: Cross-Classification of Algorithms and Reference Blood Pressure Results-Notification Analysis Set

	Baseline blood pressure results		
	Hypertension	Non-hypertension	Total

This product	With Notification	243	100	343
	Without Notification	331	1185	1516
	Insufficient data	15	68	83
	Total	589	1353	1942

The results of this clinical trial showed a sensitivity of 41.3% [95% CI (37.3%, 45.4%)] and a specificity of 92.2% [95% CI (90.6%, 93.6%)], exceeding the predefined performance goals (sensitivity 30%, specificity 90%). The positive predictive value (PPV) for AHA stage 1 or 2 hypertension subjects was 70.8% (95% CI (65.7%, 75.6%), the sensitivity for stage 2 hypertension subjects was 53.9% (95% CI (47.9%-59.8%)), and the false-positive rate (FPR) for normotensive subjects was 4.7% (95% CI (3.5%, 6.2%)).

Table 2: Primary Endpoint Analysis of Sensitivity and Specificity-Notification Analysis Set

Result of the algorithm		Two-sided 95% CI
Sensitivity	243/589 （41.3%）	（37.3%、45.4%）
Specificity	1185/1285 （92.2%）	（90.6%、93.6%）

The results of the analysis of sensitivity and specificity after covariate adjustments are presented as risk ratios in Table 3. For each demographic characteristic evaluated, the first subcategory in the table is the numerator of the risk ratio.

Table 3: Risk Ratios for Sensitivity and Specificity with Covariate Adjustment by Demographic Subgroups-Notification Analysis Set

Exploratory analyses among the subgroups		Sensitivity risk ratio [95% CI]	Specificity risk ratio [95% CI]
Age	<60 yr vs. ≥ 60 yr	0.68 [0.55, 0.84]	1.09 [1.04, 1.15]
Sex	Female vs. Male	0.93 [0.77, 1.12]	0.97 [0.93, 1.01]
Race	Not White vs. White	0.88 [0.70, 1.10]	1.04 [1.01, 1.07]

	Not Black vs. Black	1.19 [0.92, 1.53]	0.97 [0.93, 1.01]
	Not Asian vs. Asian	1.42 [0.86, 2.35]	1.00 [0.97, 1.04]
BMI	≦30 vs. >30 kg/m²	0.66 [0.55, 0.80]	1.06 [1.02, 1.11]
Fitzpatrick skin type classification	I-IV vs.V-VI	1.09 [0.83, 1.44]	0.98 [0.94, 1.02]

Older age (≧60 years) and higher BMI (>30 kg/m2) subjects had higher sensitivity and lower specificity. There were no clinically significant differences after covariate adjustment for sex, race, or skin color comparison.

The only adverse events related to the study procedure were arthralgia, rash, and skin reactions, all of which were related to wearing the Watch. No serious adverse events were considered possibly or clearly related to the study procedure.

2. Review Results

As a result of the review of the submitted data, PMDA concluded that the product could be approved for the following intended use shown below with the following approval conditions.

<Intended Use>

Apple's Hypertension Notification Feature analyzes the data obtained by photoplethysmography, detects patterns suggestive of hypertension, and notifies the user. This product is a home use program for users aged 22 years and over who have never been diagnosed with hypertension.

<Conditions for Approval>

The applicant is required to work with related academic societies and to take necessary measures to ensure that users and healthcare professionals understand the characteristics and clinical positioning of the product and use the product appropriately.