Review Summary

July 23, 2026

Pharmaceuticals and Medical Devices Agency

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	:	Analyzing software for hemodynamics or cardiac function
Brand name	:	Cardiac CT Image Analysis Software FFR
Applicant	:	CLAIRVO TECHNOLOGIES Inc.
Date of application	:	May 30, 2025
Date of approval	:	March 5, 2026
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 an analyzing software for hemodynamics or cardiac function, intended to support diagnosis by processing information obtained from coronary computed tomography angiography (hereinafter referred to as "CCTA") and calculating the fractional flow reserve (hereinafter referred to as "FFR") through hemodynamic analysis in clinically stable patients with suspected coronary artery disease.

The calculation of FFR is used in cases where it is difficult to determine the necessity of coronary angiography or treatment for coronary artery disease based solely on the results of CCTA.

(2) Non-clinical Data

The following nonclinical data were submitted.

- Algorithm performance evaluation tests
- Functional verification tests
- Software Lifecycle Process documentation demonstrating compliance with IEC 62304:2006/Amendment 1:2015
- Usability Engineering Process documentation demonstrating compliance with the Chinese standard YY/T 1474-2016
- Cybersecurity documentation demonstrating compliance with IEC 81001-5-1:2021

(3) Clinical Data

As clinical study results for this product, the applicant submitted the results of a performance evaluation study using existing medical information from China.

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.

<Intended Use>

This program is intended to support diagnosis by processing information obtained from CCTA and calculating FFR through hemodynamic analysis in clinically stable patients with suspected coronary artery disease.

The calculation of FFR is used in cases where it is difficult to determine the necessity of coronary angiography or treatment for coronary artery disease based solely on the results of CCTA.