

Review Summary

September 15, 2026

Pharmaceuticals and Medical Devices Agency

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

Classification	:	Instrument & Apparatus 21, Organ function testing apparatus
Term name	:	Multiparameter monitor with critical parameters
Brand name	:	HemoSphere Alta Advanced Monitoring Platform
Applicant	:	Edwards Lifesciences Limited
Date of application	:	May 30, 2025
Date of approval	:	April 8, 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

The product is a multiparameter monitor with critical parameters that measures or calculates hemodynamic parameters and oxygen-analysis parameters, such as thermodilution cardiac output, blood temperature, right ventricular cardiac output, arterial pressure-based cardiac output, blood pressure, venous oxygen saturation, tissue oxygen saturation, and relative change in hemoglobin or total hemoglobin concentration of the blood, in order to collect and monitor various types of biological information. In addition, in non-cardiac surgery, it displays the Hypotension Prediction Index (hereinafter referred to as “HPI”) based on the measured arterial pressure waveform and the physical information of the patient. The product differs from the applicant’s own approved product “HemoSphere Advanced Monitoring Platform” (Approval No. 30200BZX00403000) in that each module, which used to be connected to the module expansion slots on the back of the main unit, has been integrated into the main monitor to construct a single platform, and in that measurement functions such as right ventricular pressure / right ventricular cardiac output, pulmonary artery occlusion pressure, relative change in hemoglobin, total hemoglobin concentration, Global Hypoperfusion Index (hereinafter referred to as “GHI”), and Cerebral Autoregulation Index (hereinafter referred to as “CAI”) have been added. However, the intended use and the method of use, etc. are substantially equivalent, and there is no particular novelty.

(2) Non-clinical Data

The following non-clinical data were submitted (data items were based on applicant submission data). Some of the performance evaluation tests were treated as non-clinical data based on Specific Handling 2(1) of the “Handling of Performance Evaluation Tests for Diagnostic Medical Devices Using Existing Medical Image Data, etc. Without Additional Invasion or Intervention” (PSEHB/MDED Notification No. 0929-1 dated September 29, 2021).

- Electrical safety and electromagnetic compatibility: Materials demonstrating conformity with IEC 60601-1:2005/AMD2:2020, IEC 60601-1-2:2014/AMD1:2020, and IEC 60601-1-8:2006/AMD2:2020

- Software life cycle process: Materials demonstrating conformity with IEC 62304:2006/AMD1:2015
- Usability engineering process: Materials demonstrating conformity with IEC 60601-1-6
- Cybersecurity: Materials demonstrating conformity with IEC 81001-5-1
- Mechanical safety: Materials demonstrating conformity with IEC 60601-1:2005/AMD2:2020
- Stability and durability: Omitted based on the “Handling of Stability Testing Related to the Setting of Shelf Life for Applications for Marketing Approval (Certification) of Medical Devices” (PFSSB/MD Notification No. 1227-5 dated December 27, 2012)
- Performance: Tests on the measurement accuracy of thermodilution cardiac output; measurement accuracy of continuous cardiac output; measurement accuracy of invasive and non-invasive arterial pressure-based cardiac output; measurement accuracy of mixed venous oxygen saturation and central venous oxygen saturation; measurement accuracy of tissue oxygen saturation (body surface, brain); sensitivity and specificity of HPI, GHI, and CAI; measurement accuracy of pulmonary artery occlusion pressure, right ventricular pressure, and right ventricular cardiac output; measurement accuracy of relative change in hemoglobin and total hemoglobin concentration; and gesture function and voice function, etc.
- Animal Test: Test results using a porcine hypotension model related to CAI

(3) Clinical Data

As the clinical trial results of the product, the applicant submitted the results of a performance evaluation test using existing overseas clinical information. The outline of the study is as follows (with reference to the “Clinical Results” section of the package insert). The test was treated as clinical data based on Specific Handling 2(2) of the “Handling of Performance Evaluation Tests for Diagnostic Medical Devices Using Existing Medical Image Data, etc. Without Additional Invasion or Intervention” (PSEHB/MDED Notification No. 0929-1 dated September 29, 2021).

1. Objectives

To evaluate the validity of characterizing the performance of the CAI algorithm as an indicator of the state of cerebral autoregulation and of intending it as a surrogate measurement of cerebral autoregulation.

2. Study design

Retrospective analysis using overseas clinical data.

3. Test method

The determination of the patient’s state, made by setting the CAI threshold at 45, was compared with the cerebral autoregulation status classification derived from the lower and upper limits of autoregulation (LLA

and ULA), which were determined from the relationship between cerebral blood flow velocity (CBFV) and mean arterial pressure (MAP), and the sensitivity, specificity, and AUC were calculated.

4. Test result

Table 1. ROC analysis results for clinical data (N=50)

CAI threshold	Sensitivity (%) [95% CI]	Specificity (%) [95% CI]	ROC AUC [95% CI]
45	82 [75, 88]	94 [91, 96]	0.92 [0.89, 0.94]

5. Conclusion

At a CAI threshold of 45, both the sensitivity and specificity were 80% or higher, demonstrating that the state in which cerebral autoregulation is not impaired can be distinguished from the state in which cerebral autoregulation is impaired.

2. Review Results

PMDA reviewed the submitted data, taking into account that the product is a next-generation model of the applicant's own approved product; that its basic principles and method of use as a monitor are substantially equivalent to those of the approved product; that, for the additional parameters not present in the approved product, it has been demonstrated that the specification values established through design verification and design validation are satisfied; and that the performance of CAI has been confirmed by the submitted clinical evaluation data. As a result of the review of the submitted data, PMDA concluded that the product could be approved for marketing.

<Intended Use>

The product is a multi-parameter monitor for collecting and monitoring various types of biological information by measuring or calculating hemodynamic parameters and oxygen-analysis parameters, such as thermodilution cardiac output, blood temperature, right ventricular cardiac output, arterial pressure-based cardiac output, blood pressure, venous oxygen saturation, tissue oxygen saturation, and relative change in hemoglobin or total hemoglobin concentration of the blood.

In addition, in non-cardiac surgery, it displays the Hypotension Prediction Index based on the measured arterial pressure waveform and the physical information of the patient. When the Hypotension Prediction Index is calculated by invasive measurement, a dedicated sensor connected to a catheter, etc. indwelled in the patient's artery is used. When the Hypotension Prediction Index is calculated by non-invasive measurement, a dedicated finger cuff attached to the patient's finger is used.