Review Summary

July 23, 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	:	Program 1, Diagnostic Program
Term name	:	Supporting software for detecting lesion with endoscopic imaging
Brand name	:	Endoscopic Image Diagnostic Support Software AP01
Applicant	:	AI Medical Service Inc.
Date of application	:	November 27, 2025
Date of approval	:	May 13, 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 supporting software for detecting lesion with endoscopic imaging used for identifying regions suspicious for early gastric cancer or adenoma in gastric endoscopy videos and present them to physicians, thereby drawing attention to potentially suspicious areas and assisting interpretation and lesion detection. The purpose of developing this product is twofold: first, to bring to market a product equipped with a user interface equivalent to that of products already approved by other manufacturers; and second, based on the company's own previously approved product, "Endoscopic Image Diagnosis Support Software gastroAI" (Approval No. 30600BZX00266000), to improve AI performance and expand the range of compatible endoscope systems, thereby enabling a broader range of medical institutions to benefit from detection support for gastric neoplastic lesions.

(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 applicant submitted the results of a clinical performance study using clinical data obtained from routine clinical practice in Japan. The outline of the study is as follows.

A retrospective performance evaluation test was conducted on lesions diagnosed as early gastric cancer (protruded type, flat type, depressed type) and adenoma based on gastric endoscopy videos and pathological information, and the primary endpoint of the lesion detection support function of this product was evaluated as sensitivity.

【Test Result】

Table 1. Sensitivity (Primary Endpoint) and Specificity (Secondary Endpoint)

Number of Samples	Primary Endpoint	Secondary Endpoint
	Sensitivity (%) One-sided 97.5% LCL	Specificity (%) One-sided 97.5% LCL
1099 With detection target: 569 findings Without detection target: 530 videos	94.6 (92.4)	94.3 (92.0)

* LCL : lower confidence limit

Table 2 Sensitivity and Specificity by Finding/Macroscopic Classification

Finding/Macroscopic Classification		Sensitivity [%]/ Specificity [%]	One-sided 97.5% LCL
With detection target	Early gastric cancer (protruded type)	95.4	90.7
	Early gastric cancer (flat type)	89.7	76.4
	Early gastric cancer (depressed type)	95.0	92.2
	Adenoma	90.9	72.2
Without detection target	No findings	99.1	95.2
	Polyp	92.7	86.2
	Atrophic gastritis and gastritis	93.0	89.3
	Gastric ulcer (including scar)	94.4	81.9

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 product identifies regions suspicious for early gastric cancer or adenoma in gastric endoscopy videos obtained by physicians for the purpose of lesion detection and presents these videos to physicians, thereby drawing attention to potentially suspicious areas and assisting physicians in interpreting the videos to detect lesions.

The intended use of this product is to assist physicians in lesion detection, and it is not intended to support qualitative diagnosis or to determine treatment strategies based solely on the analysis results generated by this product.