Review Summary

May 19, 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	:	Diagnostic assistant device for pathological whole slide image
Brand name	:	Leica Aperio GT450 DX
Applicant	:	Leica Microsystems
Date of application	:	May 12, 2025
Date of approval	:	February 3, 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 a diagnostic assistant device for pathological whole slide image used for assisting pathologists in evaluating and diagnosing digital pathological tissue images through automatic capture, display, and storage of pathological whole slide images. The purpose of development of this product is to maximize throughput and image quality yield while minimizing user operation time, based on the approved product "Leica Virtual Slide System AT2 DX" (Approval No. 30200BZX00381000).

(2) Non-clinical Data

The following non-clinical data were submitted (data items are based on applicant submission data).

- Electrical safety and electromagnetic compatibility: data indicating conformity with IEC 61010-1:2010+AMD1:2016, IEC 61010-2-101:2018, IEC/EN 61326-2-6:2021, EN 61326-1:2013
- Performance: studies conducted in accordance with FDA guidance "Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices (April 20, 2016)"
- Software Lifecycle Process: data on conformity to IEC 62304:2006+A1:2015
- Usability Engineering: data on conformity to IEC 62366-1:2015+A1:2020
- Cybersecurity: data on conformity to JIS T 81001-5-1:2023

(3) Clinical Data

The applicant submitted a clinical evaluation report centered on an Accuracy Clinical Study conducted in the United States. The outline of the Accuracy Clinical Study is as follows (the clinical results section of the package insert is cited, and table numbers are modified as necessary).

Accuracy Clinical Study

1. Objectives

To verify major discrepancy between pathological diagnosis performed using this product and diagnostic results with optical microscopy.

2. Study design

A non-interventional multicenter study in which 1,152 cases were randomly assigned to multiple pathologists selected from 3 sites for diagnosis, compared using two different methods WSIR and MSR, and statistically evaluated more than 1,000 cases of various tissue/organ types.

3. Test method

Of the 1,152 evaluable cases, 3,549 WSIR diagnoses and 3,631 evaluable MSR diagnoses were statistically analyzed, and reading pathologists at each site evaluated all study cases at their respective sites using this product and performed WSIR diagnoses.

4. Test results

Full cohort (combination of local cohort and remote cohort):

The major discrepancy rate observed in WSIR diagnosis was 6.14% (218/3549), and 3.66% (133/3631) in MSR diagnosis. The major discrepancy rate estimated by the generalized linear model was 5.84% (95% CI: 5.01%–6.80%) for WSIR diagnosis and 3.44% (95% CI: 2.84–4.17%) for MSR diagnosis.

The estimated difference in major discrepancy rate (WSIR diagnosis minus MSR diagnosis) was 2.40% (95% CI: 1.40%–3.39%). The upper limit of the 95% CI of the estimated difference in major discordance rate was 3.39%, which met the predefined acceptance criterion of ≤4%.

The secondary endpoint was to demonstrate that the major discrepancy rate between WSIR diagnosis and reference diagnosis did not exceed 7%. The upper limit of the 95% CI of the major discrepancy rate for WSIR diagnosis was 6.80%, which met the predefined criterion of 7% or less. See tables below.

Table 1 Major discrepancy rates for MSR diagnosis and WSIR diagnosis

		WSIR diagnosis				MSR diagnosis				Difference in discordance rate	
Cohort		Major Discrepancy	Total	Major Discrepancy Rate	Model 95% CI (%)	Major Discrepancy	Total	Major Discrepancy Rate	Model 95% CI (%)	%	Model 95% CI (%)

				(%)				(%)			
Full	Observed	218	3549	6.14		133	3631	3.66			
	Model			5.84	(5.01, 6.80)			3.44	(2.84, 4.17)	2.40	(1.40, 3.39)

Table 2 shows the discrepancy rate by MSR diagnosis and WSIR diagnosis by organ.

Table 2 discrepancy rate by MSR diagnosis and WSIR diagnosis by organ

Organ type	Major Discrepancy Rate		Difference in Major Discrepancy Rate (%)
	WSIR diagnosis	MSR diagnosis	
Anus/perianal	7.26%	3.23%	4.03%
Appendix	0.00%	0.00%	0.00%
Bladder	14.79%	12.87%	1.93%
Brain/Neuro	2.90%	6.02%	-3.13%
Breast	7.62%	3.61%	4.01%
Colorectal	2.18%	1.42%	0.76%
Endocrine	6.47%	3.53%	2.94%
GE junction	2.91%	4.65%	-1.74%
Gallbladder	0.00%	0.00%	0.00%
Gyn	5.22%	4.69%	0.53%
Hernia/Peritoneal	0.00%	0.00%	0.00%
Kidney, Neoplastic	3.13%	1.03%	2.09%
Liver/BD	4.55%	1.39%	3.16%
Lung	7.11%	2.02%	5.09%
Lymph Node	2.76%	2.27%	0.49%
Prostate	6.80%	4.03%	2.76%
Salivary gland	1.43%	1.37%	0.06%
Skin	10.57%	2.87%	7.70%
Soft Tissue Tumor	6.90%	3.41%	3.49%
Stomach	3.97%	3.27%	0.71%

2. Review Results

PMDA concluded that efficacy and safety of the product could be largely explained in non-clinical studies. Considering that some clinical use experience is shown in the clinical evaluation report, PMDA concluded that the product could be approved.

<Intended Use>

The Leica Aperio GT450 DX is a system used to assist pathologists in evaluating and diagnosing digital pathological tissue images through automatic capture, display, and storage of pathological whole slide images.

This product is intended for use with pathological slide samples prepared from formalin-fixed paraffin-embedded (FFPE) tissue and is not intended for use with frozen section samples, cytological samples, or non-FFPE blood samples.