Review Summary

May 19, 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	:	Instrument & Apparatus 25, Medical Scope
Term name	:	Capsule imaging and tracking device
Brand name	:	PillCam COLON 2 Capsule Endoscopy System
Applicant	:	Covidien Japan Inc.
Date of application	:	April 18, 2025
Date of approval	:	December 19, 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

The product is a capsule imaging and tracking device to provide images for the diagnosis of colorectal disease. The data captured by the capsule endoscope is processed by software to create a video that deletes images deemed to be of low clinical significance. It also has a Quick-view function to select frames suspected of containing a polyp or a red lesion, and a Collage-view function to trim and display sections of a suspected polyp.

The purpose of this submission is to update the software to improve the ability to delete images deemed to be of low clinical significance and to accommodate the new OS due to the end of support.

(2) Non-clinical Data

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

- Electrical safety and electromagnetic compatibility: data indicating conformity with IEC 60601-1:2005/AMD1:2012/AMD2:2020、IEC 60601-1-2:2014/AND:2020
- Biological safety: Omitted based on identity with the approved product
- Mechanical safety: Omitted based on the identity with the approved product
- Stability and durability: Omitted based on the identity with the approved product
- Performance: Documents that evaluate the proper operation of software functions
- Software Lifecycle Process: data on conformity to IEC 62304:2006/AMD1:2015
- Cyber security: data on conformity to IEC 81001-5-1:2023
- Usability engineering process: data on conformity to IEC 62366-1:2015/AMD 1:2020

(3) Clinical data

The applicant submitted a clinical evaluation report on algorithm validation tests based on data collected from clinical studies conducted in the United States and other countries. The outline of the data submitted is as follows.

For the video generation function for deleting less clinical important images, the number of frames to be deleted and the sensitivity of polyp detection were similar to those of approved product. In addition, the accuracy of polyp detection in Quick-view and Collage-view was similar to that in approved product.

2. Review Results

PMDA concluded that the application for approval based on the clinical evaluation report is acceptable based on the following considerations comprehensively: the clinical study based on the data used in algorithm validation tests was conductedunder management at least equivalent to "Ministerial Ordinancee on Good Clinical Practice for Medical Devices Ordinance" of Japan; ; and the domestic share of the product is approximately 100% and a stable supply is required.