



CapsoVision's CapsoCam Plus® Capsule Endoscopy System Earns FDA Clearance to Continue Remote Ingestion, Further Expanding Access and Comfort for Patients

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Saratoga, CA – January 9, 2025 – CapsoVision, Inc., a leader in innovative endoscopic capsule technology, today announced that its award-winning product, the CapsoCam Plus® capsule endoscopy system, has received U.S. Food & Drug Administration (FDA) clearance for remote ingestion. This milestone allows patients to conveniently ingest the CapsoCam Plus capsule from the comfort of their homes under virtual medical supervision, representing a transformative step in enhancing patient accessibility and comfort in diagnostic procedures for small bowel visualization.

CapsoCam Plus is unique in that it typically does not require a visit to a hospital or clinic – unlike competing capsule endoscopy systems, which require two visits: one for ingestion and another to return the equipment. With the recent remote ingestion clearance by the FDA, eligible patients can now avoid clinic visits entirely. They can ingest the capsule from the comfort of their own home and go about their day without any external data recording equipment. The wire-free onboard storage design makes capsule administration faster and easier, while streamlining the workflow for physicians and their practices. This convenience makes the CapsoCam Plus system an ideal tool for expanding care through telehealth and reducing the burden on both patients and healthcare providers.

The remote ingestion of the CapsoCam Plus capsule is practiced in medical centers serving patients in remote regions of Canada, with favorable outcomes reported in the literature (*Journal of the Canadian Association of Gastroenterology*, 2021)¹. And in 2020, CapsoVision received enforcement discretion from the FDA during the COVID-19 pandemic for patients determined eligible for at-home administration in the U.S. The labeling addendum permitted a fully remote capsule endoscopy procedure for eligible patients, eliminating the need for in-person interaction between clinic staff and patients. The new FDA clearance allows patients to continue to ingest the CapsoCam Plus capsule beyond the initial flexibility granted during the pandemic.

“We are honored to announce the FDA’s clearance to continue remote ingestion of CapsoCam Plus,” said Johnny Wang, President and CEO of CapsoVision. “By offering a remote option, healthcare providers can significantly enhance patient convenience and broaden the scope of accessible care.”

This milestone for both patients and physicians is supported by a robust protocol for remote ingestion of the small camera device to ensure the same high standard of care that patients receive in a clinical setting. Study participants reported that the capsule is easy to swallow and preferred by patients² over other capsule endoscopy systems. Patients begin the process with a Risk Assessment Patient Questionnaire to assess any potential risks associated with capsule ingestion. During a scheduled virtual visit, a healthcare provider verifies the patient’s readiness, checks the capsule packaging, and guides the patient step-by-step through the ingestion process, providing real-time supervision to ensure a safe procedure. After ingestion, the provider monitors the patient remotely, with an accompanying adult present to assist if needed. This careful oversight allows patients to undergo capsule endoscopy safely while remaining in the comfort of their homes.

CapsoCam Plus is designed for high-resolution, panoramic visualization of the small bowel mucosa, providing physicians with a comprehensive tool to detect abnormalities. CapsoCam Plus stands out as the only capsule endoscopy system with four cameras, capturing a 360° panoramic view of the small bowel to enhance visibility and diagnostic accuracy. Unlike traditional capsule endoscopes with a single forward-facing camera that can miss important details, CapsoCam’s comprehensive imaging technology minimizes the chance of missed lesions by capturing high-resolution images of the entire small bowel. This advantage allows physicians to examine critical areas of the mucosa more thoroughly, improving visibility and diagnostic confidence.

In addition to higher lesion detection, CapsoCam Plus eliminates the need for external equipment, such as recorders or sensor belts, which can be inconvenient for patients. With CapsoCam Plus, patients ingest the capsule without being fitted with any equipment, allowing them to continue their daily routines while the capsule gathers diagnostic data within the digestive tract. This streamlined, patient friendly design reduces anxiety and discomfort, making the experience more comfortable and manageable.

“CapsoVision is completely changing the game by offering 360° panoramic imaging, providing a comprehensive view of the small bowel mucosa, combined with the ease of use of remote ingestion and streamlined workflows for physicians. This advancement demonstrates our continued commitment to transforming diagnostic accuracy, patient experience, and practice efficiency,” said Doug Atkinson, Senior Vice President at CapsoVision.

¹ Remote Capsule Endoscopy: Outcomes and Feasibility (*Journal of the Canadian Association of Gastroenterology*, 2021). Available at: <https://pmc.ncbi.nlm.nih.gov/articles/PMC8697548/>.

² Comparison of CapsoCam® SV-1 to PillCam® SB2 in the Evaluation of Subjects with Suspected Small Bowel Disease – 510K Clearance.