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First cloud-based AI endoscopy system for colonoscopy gets US FDA clearance

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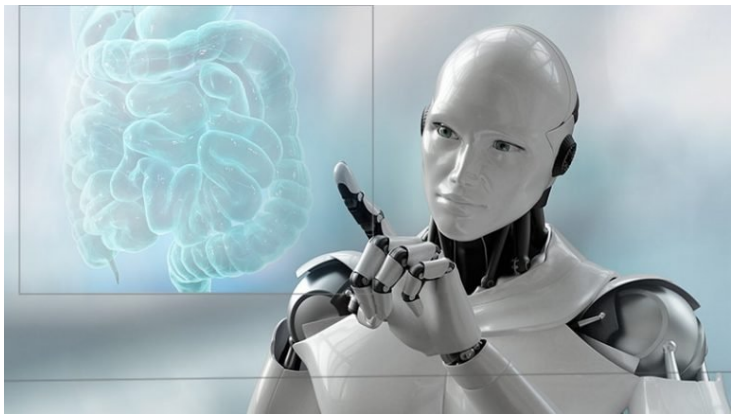
Leveraging the power of cloud and AI to improve clinical outcomes



Odin Medical, an Olympus Corporation company, has received US Food and Drug Administration (FDA) 510(k) clearance for the first cloud-based Artificial Intelligence (AI) technology designed to assist gastroenterologists in detecting suspected colorectal polyps during colonoscopy procedures, the CADDIE computer-aided detection (CADe) device.

A prospective, multi-centre randomised controlled trial successfully demonstrated the efficacy and safety of the CADDIE device, underscoring its potential to enhance detection capabilities and patient care without increasing procedural risks or duration. The trial was conducted across eight medical centres in Europe.

The CADDIE device works by analysing colonoscopy video in real-time and using visual markers to alert the endoscopist to the potential presence of polyps. The endoscopist is responsible for reviewing the CADDIE device's suspected polyp areas and confirming the presence or absence of a polyp based on their own medical judgment.

Supporting advancements in colorectal cancer screening and detection, Japan-based Olympus aims to reduce the societal burden of lives lost to colorectal cancer, which is expected to claim more than 53,000 lives in the US in 2024 and is the second-leading cause of cancer deaths among men and women in the US.

Improving the effectiveness of colonoscopy, considered the gold standard for colorectal screening, by strengthening clinical decision-making is one of the primary goals of the Olympus Intelligent Endoscopy Ecosystem, which will leverage the CADDIE device's cloud connectivity and AI capabilities. The CADDIE device is limited to use with standard white-light endoscopy imaging only.