Health Technology Review	
Technology Ref.:	**HTA21018**
Technology Name:	**GI Genius Artificial Intelligence System for Colonoscopy**
Approvals by International Bodies:	**FDA & CE IVD**
Company name:	**Sheikh Shakbout Medical City**
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Short Description of the Technology:	GI Genius Artificial Intelligence System is a system for colonoscopy of a small device and AI software which helps in the high detection of precancerous polyps and helps to provide state of the art cancer/cancer prevention services.

Health Technology Assessment Team Recommendation:	**Approved with limitation**

Summary of Review:

GI Genius Artificial Intelligence System is the only approved device by FDA for the use of endoscopy and it can help a lot in the fast detection of precancerous and it will serve as a great aid in the gastroenterology field. The device uses algorithm techniques to identify regions of interest. During a colonoscopy, the GI Genius system generates indicators and highlight them on the video from the endoscope camera.

Advantages	Disadvantages
significantly increase adenoma detection rate by 10-12%	The device does not provide any diagnostic assessments of colorectal polyp pathology, nor does it suggest to the clinician how to manage suspicious polyps
improve the quality of colorectal cancer screening	additional clinical data will be needed to demonstrate its efficacy, value, and impact on patient care and outcome.
FDA approved	Maintenance and repair costs
Safe to the patients and doesn't present any imminent hazards	Local cost effectiveness study not provided
As per international cost effectiveness study done it shows cost saving strategy to further prevent CRC incidence and mortality.	Not clear if using the technology will increase the cost of the procedure

HTA Recommendation:

We recommend an **Approval with Limitation for market use** only with the following conditions:

1. Obtaining the approval of DOH-HSF if requires the coverage of Thiqa
2. Ensuring the dataset residency and access are compliant to the applicable Laws & Regulations.
3. Additional information is required on how the dataset is kept updated.

4. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees and Patient
5. Provision of regular updates and reports about the product to DOH upon request.
6. Any other documents or information requested regarding the product and cost to finalize the approval process.

Moreover, DOH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.

Technology Image