



Health Technology Review	
<b>Technology Ref.:</b>	HTA23080
<b>Technology Name:</b>	Endofresh Disposable Digestive Endoscope System, Device
<b>Approvals by International Bodies:</b>	US FDA, MoHaP and NMPA (China)
<b>Company name:</b>	Hayat Biotech Ltd
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<b>Short Description of the Technology:</b>	Endofresh Disposable Digestive Endoscope System, Device is a single use GI endoscopes are disposable / non-reusable endoscopes used to visualize the gastro-intestinal tract internally. By being disposable it eliminates the risk of cross-infection.
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<b>Health Technology Assessment Team Recommendation:</b>	<b>Approve</b>
<b>Summary of Review:</b>	
<p>The EndoFresh system is a disposable endoscope designed for gastrointestinal procedures. It aims to reduce the risk of cross-contamination and enhance patient safety by providing a single-use, high-quality imaging alternative to traditional reusable endoscopes.</p> <p>European Society of Gastrointestinal Endoscopy (ESGE) recommendations single use endoscopies should only be considered in highly selected patients on a case-by-case basis such as those who are immunocompromised or have MDROs.</p>	
<b>Advantages</b>	<b>Disadvantages</b>
Reduced infection risk by eliminating the risk of cross-contamination between patients, crucial in infection control.	The disposability of the endoscope contributes to medical waste.
Saves time and resources as no cleaning or sterilization is required	More expensive over time compared to reusable endoscopes, considering each endoscope is used only once.
Each new endoscope is likely to provide consistent imaging and functionality, without the wear and tear associated with reusable scopes.	Relies on a steady supply for continuous use, which could be an issue in case of manufacturing or supply disruptions.
Useful in emergency situations where a sterilized endoscope might not be readily available.	Disposable scopes might not offer the same advanced features or customizability as some high-end reusable models.

We recommend an **approval of using this technology** for Market entry with the following conditions:

1. Approval for Endofresh Disposable Digestive Endoscope System, Device version/model number XZING-W200B (Disposable GI Colonoscope)/ XZING-W200B (Disposable GI Colonoscope) / XZING-S2 (Camera System).
2. Using the technology may only be started after completion of the required training from a qualified instructor.
3. Should only be performed in highly selected patients on a case-by-case basis such as those who are immunocompromised or have MDROs.
4. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
5. Provision of regular updates and reports about the product to DOH upon request.

**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



### Population, setting and intended user for Technology “Endofresh Disposable Digestive Endoscope System, Device”

- **Population/ Intended User;**
  - Recommended for high-risk patients where infection control is paramount.
- **To be performed by:**
  - Trained medical professionals.
- **Clinical Setting:**
  - Hospitals, outpatient clinics, and any healthcare settings equipped for endoscopic procedures.
- **Condition of use:**
  - The system is designed for single-use applications, thereby ensuring a sterile device for each patient. It's particularly useful in settings with high patient turnover or limited sterilization facilities.



■ **Exclusion criteria:**

- Not suitable for complex endoscopic procedures requiring advanced endoscopic tools or capabilities that reusable endoscopes offer.