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RNT Health Insights receives US FDA breakthrough device designation for early gastric cancer detection tool

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Solution designed to detect lesions present in the upper gastrointestinal tract



Chandigarh-based RNT Health Insights, a clinical stage medical diagnostics startup, has announced that the US Food and Drug Administration (FDA) has granted Breakthrough Device Designation for their Early Gastric Cancer detection tool.

The innovative solution is designed to detect lesions present in the upper gastrointestinal tract indicative of Early Gastric Cancer, as well as gastric malignancy, inclusive of gastric atrophy, nodules, polyps, masses and growths present in the stomach, in real-time during standard endoscopy examinations.

Gastric cancer is the fourth leading cause of cancer related mortality across the globe, with a five-year survival rate of less than 40%. However, it is reported that the early accurate detection of gastric cancer can increase the 5-year survival rate to 90%.

Despite gastrointestinal endoscopic procedures being the gold standard method for the diagnosis of this disease, the current miss rate for the diagnosis of Gastric cancers during these procedures stands at 4.6-25.8%, depending upon the endoscopists' experience and visual observations.

RNT Health Insights' Early Gastric Cancer detection technology can be used in real-time during endoscopic procedures to detect these pathologies, and currently displays a detection accuracy of 96% in accordance with the preclinical validation conducted. With the Breakthrough Device Designation, RNT Health Insights will benefit from an expedited review pathway to obtain the necessary permits for marketing their device. The company anticipates this will accelerate the timeline for bringing their innovative tool to market, ultimately benefiting patients and healthcare providers.