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RNT Health Insights receives second US FDA breakthrough device designation for oesophageal cancer detection tool

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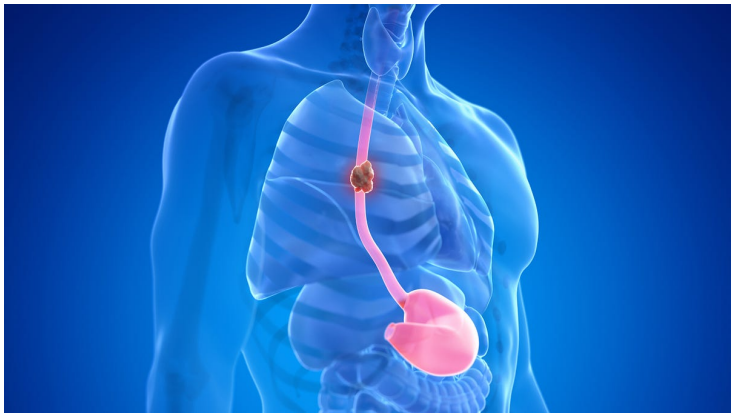

RNT Health Insights, a Chandigarh-based health-tech startup specialising in AI-assisted diagnostic solutions for the accurate detection of pathologies during endoscopic procedures, has been granted its second US FDA Breakthrough Device Designation for its Oesophageal Cancer detection tool.

This tool aids gastroenterologists in the real-time detection and identification of early-stage and advanced esophageal cancers during standard white-light upper GI endoscopy procedures.

Oesophageal cancer is the fourth leading cause of cancer-related deaths in India, and the sixth leading cause of cancer-related deaths worldwide, claiming over 540,000 lives annually. Its prognosis is notably poor, with a five-year survival rate of less than 20%. This is primarily due to the associated high miss rate of detection during early stages and attributed to the fact that it is almost always detected at an advanced stage.

Research underscores that early and accurate detection significantly improves survival outcomes; in some cases, the 5-year prognosis can improve to 90%. Despite advances in endoscopic technologies, early-stage detection of oesophageal cancer is challenging, with studies indicating that up to 25% of oesophageal cancer-related pathologies may be missed during routine endoscopic procedures.

RNT Health Insights' tool effectively aids in detecting subtypes such as adenocarcinoma, and dysplasia associated with Barrett's oesophagus. While not intended to replace clinical decision-making, this technology integrates into existing clinical workflows, ensuring endoscopists can maintain full control over decision-making while benefiting from enhanced diagnostic support. This tool intends to greatly improve the accuracy of detection of early-stage lesions, reducing the missed detection rate thereby significantly improving patient outcomes.

With this designation, the company intends to accelerate timelines for approval and market access and gain access to early feedback and support from patient advocacy groups and payor organizations for early coverage.