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ErlySign gets US FDA breakthrough device designation for saliva-based oral cancer detection test

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India’s first saliva-based, non-invasive diagnostic solution designed to identify precancerous conditions

ErlySign, an innovative biotech startup from Nagpur, has been granted the US Food and Drug Administration (FDA) Breakthrough Device Designation for its saliva-based oral cancer early detection kit.

The designation marks a significant global regulatory milestone for the company and underscores the potential of its technology to advance early cancer detection across international markets.

The FDA Breakthrough Device Designation is awarded to medical devices that demonstrate reasonable clinical evidence of providing more effective diagnosis or treatment of life-threatening or irreversibly debilitating diseases.

ErlySign’s oral cancer detection test is India’s first saliva-based, non-invasive diagnostic solution designed to identify precancerous conditions even before visible tumours or lesions appear in the oral cavity, lips, tongue, throat, or larynx. The test requires only a 2–5 ml saliva sample and delivers results within 10–15 minutes, making it quick, painless, and easy to deploy across diverse healthcare settings.

The technology has been clinically validated through large-scale, multi-city trials conducted in collaboration with Healthcare Global (HCG) and the Regional Cancer Hospital (Rashtrasant Tukdoji Cancer Hospital), Nagpur.

The studies, conducted across approximately 1,000 patients in Nagpur, Bengaluru, and Ranchi, demonstrated 98% sensitivity and 100% specificity, validating the test’s accuracy and effectiveness.