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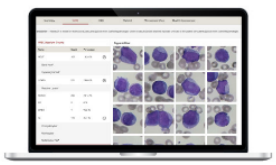
SigTupleâ??s AI100 with Shonit receives US FDA 510(k) clearance

03 October 2023 | News

SigTupleâ??s AI100 with Shonit is the premier solution for AI assisted digital pathology





SIG TUPLE

SigTuple, a Bengaluru-based medtech startup that develops Artificial Intelligence (AI) powered digital microscopy solutions, has announced that its path-breaking device AI100 with Shonit™ (Peripheral blood smear application) has received US FDA

510(k) clearance.

This is the first integrated hardware and AI medical device, and the first product in AI assisted digital microscopy from India to obtain the coveted clearance and one of the handful of companies in the world to obtain it.

For all haematological disorders like blood cancers, infections, anaemia & allergies, the microscopic examination of the peripheral blood smear (PBS) is the gold standard test, but microscopy today is predominantly a manual process - necessitating a highly skilled pathologist to be present on-site.

SigTuple's AI100 with Shonit^{TM} is the premier solution for AI assisted digital pathology, wherein a physical sample is digitally imaged through a microscopic lens & the AI models extract each cell and then classify it into over 30 different cell types. The pathologists can now review the samples remotely. Further, the AI helps make the pathologist be more efficient, by automating most of the review. Thus, the same pathologist can now handle a much larger number of samples than what she/he can currently, eliminating the need for an additional manual review.