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Singleron's Matrix NEOÃ¢â??Â¢ wins Class II medical device approval in China

November 17, 2025 | News

Regulatory milestone enables single cell sequencing to enter routine clinical diagnostics



Singleron Biotechnologies has announced that its Matrix NEO™ automated single cell processing system has received Class II Medical Device Registration approval from the Jiangsu Medical Products Administration, China.

Matrix NEO is the world's first automated single cell analysis platform to achieve medical device clearance, marking a milestone in bringing single cell sequencing from research laboratories into clinical practice.

While single cell sequencing is widely used in basic and translational research, clinical adoption has been limited by manual workflows, high costs, complex data interpretation, and regulatory uncertainty. Matrix NEO's approval validates the platform's consistent, reliable performance in single cell isolation, lysis, and mRNA capture—meeting the stringent quality standards required for clinical diagnostics.

Matrix NEO integrates with Singleron's end-to-end single cell workflow, including:

- Tissue preservation solutions for sample integrity
- PythoN® series automated tissue dissociation instruments
- Code-free bioinformatics analysis tools and clinical databases

This end-to-end automation streamlines the path from sample collection to actionable clinical insights, reducing technical variability and accelerating time-to-result.