BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Korea's Miracell receives US FDA 510(k) clearance for stem cell extraction system

April 13, 2026 | News

Blood- and bone marrow-based efficient growth factors extraction system demonstrates substantial equivalence and high cell viability



SMART M-CELL2 SMART M-CELL4

Miracell, a South Korea-based stem cell technology company, has obtained US FDA 510(k) clearance for its stem cell extraction system, **SMART M-CELL**, along with its dedicated kits, the **BSC Blood Kit** and **BMSC Bone Marrow Kit**.

The clearance was granted based on demonstrated substantial equivalence to **SmartPReP**, a globally recognised standard system originally developed by the Institute for Immunological Research (IDI) at Harvard Medical School.

The cell concentration technology utilising SmartPrep has been continuously validated through a wide range of studies and comparative analyses, with approximately 100 related publications and review articles reported to date.

Beyond musculoskeletal indications, the biological efficacy and broader applicability of cell concentration technologies have been explored across multiple therapeutic areas, including skin regeneration and aesthetics, diabetic ulcers, chronic wound healing, vascular and cardiovascular regeneration, and immune-related conditions.

While SmartPReP has been widely recognised as a high-performance concentration system, SMART M-CELL represents a significant advancement.

SMART M-CELL is an automated system that selectively separates and concentrates Efficient Growth Factors from blood and bone marrow. Beyond Efficient Growth Factors, it produces a multi-cell composition that includes growth factors, white blood cells, and SDF-1?, supporting tissue regeneration and functional recovery. The system is designed to maximise clinical applicability with high recovery rates and operational stability.

SMART M-CELL is currently the only US FDA-cleared Efficient Growth Factors extraction system from Korea. The FDA clearance, along with US patent recognition, validates Miracell's differentiated approach from Harvard-based systems and confirms its superior extraction performance and product stability.

The company added that regulatory approvals are underway in markets such as Brazil and Taiwan, and that, following the recent FDA clearance, it plans to aggressively expand into the global market, including the United States.

Miracell is a regenerative medicine company that has successfully awarded four stem cell-based new medical technologies in Korea, including treatments for cartilage defects, acute myocardial infarction, critical limb ischemia, and knee osteoarthritis. The company is also advancing efforts to expand its treatment portfolio, including the registration of a new medical technology involving concentrated autologous bone marrow stem cell injections for intervertebral disc pain.