

K250518 SMART M-CELL Bone Marrow Concentration System

Apr 2, 2026
405 days to decision

K250518 · Product code: QBV · Hematology
Source: <https://www.510kdatabase.net/k250518/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Date received	Feb 21, 2025
Decision date	Apr 2, 2026
Days to decision	405 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Miracell Co., Ltd.
Location	Seoul, KR
Contact	Sy Koo
510(k) history	2 submissions · 2 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	Mtech Group, LLC
Contact	Dave Kim

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)