

**K250516 SMART M-CELL PRP Concentration System**Apr 2, 2026  
405 days to decisionK250516 · Product code: **QBV** · Hematology  
Source: <https://www.510kdatabase.net/k250516/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mtech Group, LLC</b>
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)

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