April 2, 2026

Miracell Co., Ltd.
% Dave Kim
Medical Device Regulatory Affairs
Mtech Group LLC
7505 Fannin St. Suite 610
Houston, Texas 77054

Re: K250516
Trade/Device Name: SMART M-CELL PRP Concentration System
Regulation Number: 21 CFR 862.2050
Regulation Name: General Purpose Laboratory Equipment Labeled Or Promoted For A Specific Medical Use
Regulatory Class: Class I
Product Code: QBV
Dated: March 3, 2026
Received: March 3, 2026

Dear Dave Kim:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the

Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ying Mao -S

for

Takeesha Taylor-Bell
Deputy Directior
Division of Immunology and
Hematology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250516

Device Name
SMART M-CELL PRP Concentration System

Indications for Use *(Describe)*
The SMART M-CELL PRP Concentration System is indicated for use in clinical laboratories or intraoperatively at point-of-care for the safe and rapid extraction and transfer of platelet concentrate from a small volume of venous whole blood following centrifugal separation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary
K250516

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date prepared: March 2, 2026

I. SUBMITTER

Manufacturer:
Miracell Co.,Ltd.
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II. DEVICE

Trade/proprietary name	**:** SMART M-CELL PRP Concentration System
Common Name	: Centrifuge for preparation of cell concentrate and/or plasma concentrate
Regulation Number	: 21 CFR 862.2050
Regulation Name	: General purpose laboratory equipment labeled or promoted for a specific medical use
Regulatory Class	: Class I
Product Code	: QBV

Predicate Device :

Trade/Device Name	: SmartPReP2 Centrifuge System (K052925)
Common Name	: Syringe, Piston
Regulation Number	: 21 CFR 880.5860
Regulation Name	: Piston syringe
Regulatory Class	: Class II
Product Code	: FMF, JQC

III. PREDICATE DEVICES

The legally marketed primary predicate device for the SMART M-CELL PRP Concentrate System by Miracell is the SmartPReP2 Centrifuge System (510k number: K052925, cleared on January 4, 2006 originally cleared, and then corrected on January 13, 2016) since this device shares the same intended use of the SMART M-CELL PRP Concentrate System by Miracell (i.e., preparation of PRP from a small sample of a peripheral blood aspirate) and similar technological characteristics.

IV. DEVICE DESCRIPTION

A small amount of whole blood collected from the patient is to be loaded into the blood compartment of the Blood Separating Kit. The centrifugation cycle will separate the whole blood into erythrocytes, platelet poor plasma, and platelet rich plasma. The process involves a two-phase centrifugation cycle consisting of a primary centrifugation and secondary centrifugation. Once the two-phase separation process is complete, allowing for collection of the various blood component layers by separating based on density of liquids.

The Platelet Rich Plasma prepared by this device is for preparation of cell concentrate samples for in vitro diagnostic use and has not been evaluated for any therapeutic applications.

V. INDICATIONS FOR USE

The SMART M-CELL PRP Concentration System is indicated for use in clinical laboratories or intraoperatively at point-of-care for the safe and rapid extraction and transfer of platelet concentrate from a small volume of venous whole blood following centrifugal separation.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The SMART M-CELL PRP Concentration System is substantially equivalent to the primary predicate SmartPReP2 Centrifuge System cleared via K052925 in preparing PRP from a peripheral blood . The subject device shares the same intended use and has similar technological features as the primary predicate SmartPReP2 Centrifuge System. The following table provides a review of the similarities and differences in technological characteristics between the SMART M-CELL PRP Concentration System by Miracell and the predicate SmartPReP2 device.

Table 6-1 Substantial Equivalence Comparison

<table>
<tr><th></th><th>The SMART M-CELL PRP Concentration System
(K250516)</th><th>Primary Predicate Device
SMART PReP2 Centrifuge System (K052925)</th></tr>
<tr><td>Indications for use</td><td>The SMART M-CELL PRP Concentration System is indicated for use in clinical laboratories or intraoperatively at point-of-care for the safe and rapid extraction and transfer of platelet concentrate from a small volume of venous whole blood following centrifugal separation.</td><td>The SMART PReP2 Centrifuge System is intended to be used in the clinical laboratory or intraoperatively at point-of-care for the safe and rapid preparation of platelet poor plasma and platelet concentrate from a small sample of blood and for preparation of a cell concentrate from bone marrow</td></tr>
<tr><td>Design/Function</td><td>Platelet process kit, collection kit</td><td>Platelet process kit, collection kit</td></tr>
<tr><td>Device Material</td><td>ETHYLENE-PROPYLENE COPOLYMER</td><td>ETHYLENE-PROPYLENE COPOLYMER</td></tr>
<tr><td>Device Structure</td><td>PD(Process Disposable)chamber, Floating, Cell extraction port, Air vent, O-ring, Bonds, Cap</td><td>PD(Process Disposable)chamber, Floating, Cell extraction port, Air vent, O-ring, Bonds, Cap</td></tr>
<tr><td>Anticoagulant</td><td>Not included</td><td>Not included</td></tr>
<tr><td>Method of fluid separation</td><td>Centrifugation</td><td>Centrifugation</td></tr>
<tr><td>Buffy coat layer isolation method</td><td>Aspiration of plasma and buffy coat through a drawtube built into an internal separator. The separator starts at the top of the device and is manually moved down through the plasma and buffy coat layers separating them into the upper chamber and leaving the red blood cell in the lower chamber.</td><td>Aspiration of plasma and buffy coat through a drawtube built into an internal separator. The separator starts at the top of the device and is manually moved down through the plasma and buffy coat layers separating them into the upper chamber and leaving the red blood cell in the lower chamber.</td></tr>
<tr><td>Centrifuge Device</td><td>General purpose centrifuge
(SMART M-CELL 2/ SMART M-CELL 4)</td><td>General purpose centrifuge
(SMART PReP2)</td></tr>
<tr><td>Centrifugation Time and Speed.</td><td>Centrifugation time:
1) SMART M-CELL 2 (17 minutes)
2) SMART M-CELL 4 (20 minutes)
Speed:
1) Primary Separation: 2300RPM±150
2) Second Seperation:2200RPM±150</td><td>Centrifugation time: 14 minutes
Speed:
1) Primary Separation: 2500RPM±150
2) Second Seperation:2300RPM±140</td></tr>
<tr><td>Blood Process Kit :
(Syringe not included)</td><td>
<table>
<tr><th>Model name</th><th>A</th><th>B</th><th>C</th><th>D</th></tr>
<tr><td>BSC+③ 30</td><td>1EA</td><td></td><td>1EA</td><td>1EA</td></tr>
<tr><td>BSC+③ 60</td><td></td><td>1EA</td><td>1EA</td><td>1EA</td></tr>
<tr><td>BSC+③ 120</td><td></td><td>2EA</td><td>1EA</td><td>1EA</td></tr>
<tr><td>BSC+ ⑨ 30</td><td>1EA</td><td></td><td>1EA</td><td>1EA</td></tr>
<tr><td>BSC+ ⑨ 60</td><td></td><td>1EA</td><td>1EA</td><td>1EA</td></tr>
<tr><td>BSC+ ⑨ 120</td><td></td><td>2EA</td><td>1EA</td><td>1EA</td></tr>
</table>
</td><td>
<table>
<tr><th>Model Name</th><th>A</th><th>B</th><th>C</th></tr>
<tr><td>APC-20</td><td>1</td><td></td><td>1</td></tr>
<tr><td>APC-60</td><td></td><td>1</td><td>1</td></tr>
<tr><td>APC-120</td><td></td><td>2</td><td>1</td></tr>
</table>
A: 20mL Blood Draw Syringe Assembly
B:60mL Blood Draw Syringe Assembly
C: 10mL Syringe(Spare)
</td></tr>
</table>

Sterile, Non pyrogenic	Yes	Yes
How Sterilized	Ethylene Oxide (EO)	Ethylene Oxide (EO)
Sterility Assurance Level	10^{-6}	10^{-6}
Packaging Design	Tyvek Tray.	Tyvek Tray.
How Used	Single use only	Single use only

As note in the table above, there are many similarities between the SMART M-CELL PRP Concentration System by Miracell and the predicate SMART PReP2 Centrifuge System device. The subject device is substantially equivalent to the predicate SMART PReP2 Centrifuge System device with respect to structure, material, and general fluid separation method. The following provides additional review and discussion for each item identified in Table 6-1 in regards to the comparison of the subject and predicate SMART PReP2 Centrifuge System device.

- **Indications for Use** - The "Indications For Use" (IFU) for the predicate device and the subject device are stated and compared; consequently, the IFU of both devices are substantially equivalent. The indication for use statement for the SMART M-CELL PRP Concentration System by Miracell has been standardized to align with the predicate intended use statement.
- **Device Materials** - The subject device material is substantially equivalent to the primary predicate device: Both the subject device and the predicate are made of a molded polymer.
- **Device Structure** - The structure of the subject device and the predicate are substantially equivalent: They both consist of a thin walled, molded, cylinder shaped body of similar size.
- **Method of fluid separation -** The fluid separation method of the subject device is substantially equivalent to the predicate device using a general purpose centrifuge method of separating blood into layers based on cell density.
- **Centrifuge/Centrifugation Time and Speed** - Both the subject device and the predicate are used with a commercially available general-purpose centrifuge. The subject device creates PRP in two centrifugation steps using a single concentration container. First, the device spins at 2300 RPM, and then afterward, it spins at 2200 RPM for 17 minutes (SMART M-CELL 2) and 20 minutes (SMART M-CELL 4) .
  In contrast, the predicate system spins only once at 2500 RPM for 14 minutes.
- **Single-Use/Sterile** – The blood process kit for the subject and predicate device are single use only and sterilized via EO and labeled as non-pyrogenic.

VII. PERFORMANCE DATA

Comparative studies were performed using BSC+③ 60 and BSC+⑨ 60 kits with the SMART M-CELL 2 device at a single site. Venous whole blood samples were collected from healthy donors, and baseline cell counts were assessed prior to centrifugation. Each sample was then divided, with half processed using the subject device and the other half processed using the predicate SmartPReP2 Centrifuge System (K052925). Cell counts from the processed samples were compared to the initial baseline blood samples and evaluated side-by-side between the subject and predicate devices.

The results demonstrate that the SMART M-CELL PRP Concentration System is equivalent to the predicate device in preparing platelet concentrate, with comparable cell count profiles and platelet recovery rates.

Miracell conducted the Rotor speed test with the representative product, SMART M-CELL 2. The rotor speeds criteria of SMART M-CELL 2 and SMART M-CELL 4 are identical. The sole distinction between the two models lies in the quantity of kit basket.

To establish substantial equivalence, the optimal process conditions for rotational speed and processing time were determined by referencing the predicate device (SMART PReP2 Centrifuge System). The test focused on achieving effective separation of key blood components (Plasma, Buffy Coat, and platelet plasma) without cellular damage or hemolysis. Consequently, the specific condition that demonstrated clear separation without sample degradation was selected as the optimal setting.

Test results indicate that both SMART M-CELL 2 and SMART M-CELL 4 exhibit comparable performance to the SmartPReP2.

Summary of Technologies

The design, materials and processing methods are similar to the previously cleared SMART PReP2 Centrifuge System in K052925.

VIII. CONCLUSION

The SMART M-CELL PRP Concentration System is substantially equivalent to the primary SMART PReP2 Centrifuge System (K052925). Differences between the proposed device and the primary predicate device have been assessed according to the FDA recognized voluntary consensus standards or methods consistent with that described in a prior 510(k) and differences in characteristics do not raise questions concerning safety or effectiveness. Based on the indications for use, technological characteristics, and tests performed, it was determined that the proposed The SMART M-CELL PRP Concentration System is substantially equivalent to the primary predicate device cleared via K052925.