# 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
# DECISION SUMMARY
INSTRUMENT ONLY

## I Background Information:

### A 510(k) Number

K250516

### B Applicant

Miracell Co., Ltd

### C Proprietary and Established Names

SMART M-CELL PRP Concentration System

### D Regulatory Information

| Product Code(s) | Classification | Regulation Section | Panel |
|---|---|---|---|
| QBV | Class I | 21 CFR 862.2050 - General Purpose Laboratory Equipment Labeled Or Promoted For A Specific Medical Use | Hematology |

## II Submission/Device Overview:

### A Purpose for Submission:

Clearance of a new device

### B Type of Test:

Not applicable

## III Intended Use/Indications for Use:

**A Intended Use(s):**
See Indications for Use below.

**B Indication(s) 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.

**C Special Conditions for Use Statement(s):**
Rx - For Prescription Use Only

It is for in vitro use only.

The safety and effectiveness of this device for in vivo indications for use has not been established.

## IV Device/System Characteristics:

### A Device Description:

The SMART M-CELL PRP Concentration System consists of a centrifuge component (i.e., SMART M-CELL 2 or SMART M-CELL 4) and a Procedure Pack.

The SMART M-CELL 2/SMART M-CELL 4 centrifuges provide a two-phase centrifugation cycle consisting of a primary centrifugation and secondary centrifugation. The centrifuge speed (2300 RPM for primary separation; 2200 RPM for secondary separation) and time (6 minutes for primary separation; 11 minutes (SMART M-CELL 2) or 14 minutes (SMART M-CELL 4) for secondary separation) are fixed without any operator adjustment.

PRINCIPLE:
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 leukocyte and platelet rich plasma (L-PRP). The process involves a two-phase centrifugation cycle consisting of 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 Procedure Pack has two models: BSC+③ and BSC+⑨, each with three volumes (30, 60, and 120 mL). The process kit includes the following components:

| Process kit model | Components | Description |
|---|---|---|
| BSC+③30 Process Kit /BSC+⑨30 Process Kit | BSC+③/BSC+⑨ 30 Process Disposable (PD) (1 each) | Centrifuge barrel to separate whole blood into layers<br>In BSC+③ and BSC+⑨, Chamber 1: inject whole blood<br>Chamber 2: collect leukocyte- and platelet-rich plasma (PRP) |
| | Blunt Cannula and Cap (1 each) | Attach to a syringe to extract centrifuged cells |
| | Blunt Cannula, Spacer and Cap (1 each) | Attach to a syringe to remove platelet poor plasma (PPP) from the PD after centrifugation leaving PRP in Chamber 2. |
| | IN Blunt Cannula (1 each) | Attach to the syringe collected with whole blood and inject the blood into the PD. |
| BSC+③ 60 Process Kit /BSC+⑨ 60 Process Kit | BSC+③/BSC+⑨ 60 Process Disposable (PD) (1 each) | Same as BSC+③/BSC+⑨ 30 PD. |
| | Blunt Cannula and Cap(1 each) | |
| | Blunt Cannula, Spacer and Cap (1 each) | |
| | IN Blunt Cannula (1 each) | |
| BSC+③ 120 Process Kit /BSC+⑨ 120 Process Kit | BSC+③/BSC+⑨ 60 Process Disposable (PD) (2 each) | See BSC+③ 60 Process Kit /BSC+⑨ 60 Process Kit |
| | Blunt Cannula and Cap (2 each) | |
| | Blunt Cannula, Spacer and Cap (2 each) | |
| | IN Blunt Cannula (2 each) | |

## B Instrument Description Information:

1. Instrument Name:

   SMART M-CELL 2 and SMART M-CELL 4

2. Specimen Identification:

   Specimen identification label

3. Specimen Sampling and Handling:

   Follow CLSI GP41 or each clinical site SOP for venous whole blood collection.
   When preparing whole blood sample for centrifugation, inject ACD-A into the Process Disposable (PD) (1 mL of ACD-A for every 30 mL whole blood) in the Process Kit before adding freshly drawn venous whole blood for centrifugation. After centrifugation, discard platelet poor plasma on top.

4. Calibration:

   Factory calibrated

5. Quality Control:

Not applicable

## V Substantial Equivalence Information:

### A Predicate Device Name(s):
Smartprep2 Centrifuge System

### B Predicate 510(k) Number(s):
K052925

### C Comparison with Predicate(s):

| Device & Predicate Device(s): | K250516 | K052925 |
|---|---|---|
| Device Trade Name | SMART M-CELL PRP Concentration System | SmartPReP2 Centrifuge System |
| **General Device Characteristic Similarities** | | |
| Intended Use/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. | The SmartPReP2 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. |
| Principle of Operation | Density gradient separation by a two-phase centrifugation cycle | Same |
| Device Components | Centrifuge, disposable procedure pack | Centrifuge, disposable processing procedure pack |
| Sterilization Method for Processing Kit | Ethylene Oxide | Same |
| **General Device Characteristic Differences** | | |
| Centrifuge | SMART M-CELL 2 and SMART M-CELL 4 | SMART PReP2 |
| Centrifugation Time and Speed | Centrifugation Time: 17 minutes for SMART M-CELL 2 and 20 minutes for SMART M-CELL 4<br>Primary centrifugation: 2300 RPM<br>Second centrifugation: 2200 RPM | Centrifugation Time: 14 minutes<br>Primary centrifugation: 2500 ± 150 RPM<br>Second centrifugation: 2300 ± 140 RPM |

## VI Standards/Guidance Documents Referenced:

- ISO 11135 Second edition (2014): Sterilization of health-care products - Ethylene oxide - Requirements for the development validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2018)]
- IEC 61010-1 Edition 3.1 (2017): Safety requirements for electrical equipment for measurement control and laboratory use - Part 1: General requirements [Including: Corrigendum 1 (2019)]

## VII Performance Characteristics (if/when applicable):

### A Analytical Performance:

1. Precision/Reproducibility:

   Not applicable

2. Linearity:

   Not applicable

3. Analytical Specificity/Interference:

   Not applicable

4. Accuracy (Instrument):

   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.

   A separate rotor-speed performance test was conducted to verify the operational parameters of the SMART M-CELL 2 and SMART M-CELL 4 centrifuge systems. Testing was performed using multiple procedure packs including BSC+③ 30, BSC+③ 60, BSC+③ 120, under specified centrifugation conditions for SMART M-CELL 2 and SMART M-CELL 4. Both models met all acceptance criteria, with appropriate centrifugation results and no instances of product deviation or plasma separation observed. The results demonstrate that both device models perform consistently according to their design parameters with respect to centrifugation performance and operational functionality.

5. Carry-Over:

Not applicable

**B Other Supportive Instrument Performance Characteristics Data:**

**Disinfection Study**

A study was conducted to evaluate the antimicrobial activity of 83% ethyl alcohol against non-enveloped viruses. The study used standardized test methods to determine the log reduction in viral titer following exposure to the 83% ethyl alcohol for 5 min at room temperature. The results demonstrated that the subject device achieved significant viral inactivation, with log reduction values meeting established performance criteria for virucidal efficacy.

**Robustness Study**

The study evaluated the device's ability to withstand repeated exposure to cleaning and disinfection over its expected 5-year service life. The study employed a worst-case scenario of 6,000 cleaning and disinfection cycles on the SMART M-CELL 4 model. Testing was performed according to the cleaning and disinfection procedures specified in the user manual (83% ethyl alcohol), with comprehensive functional, display, and visual inspections conducted at 1,000-cycle intervals. All acceptance criteria were met throughout the validation, with no evidence of functional degradation, display malfunction, material damage, or corrosion observed at any inspection point. The results demonstrate that the device maintains its structural integrity and functional performance after repeated exposure to the instructed cleaning and disinfection process.

## VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

## IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.