510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY

I Background Information:

A 510(k) Number

K250518

B Applicant

Miracell Co., Ltd

C Proprietary and Established Names

SMART M-CELL Bone Marrow 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 Bone Marrow Concentration System is intended to be used in the clinical laboratory or intraoperatively at point-of-care for the safe and rapid preparation of a cell concentrate from bone marrow.

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 Bone Marrow 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:
Bone marrow collected in BmSC Transfer Bag from the patient is loaded into the separation compartment of the Bone marrow separating Kit. The centrifugation cycle will separate the bone marrow into erythrocytes, platelet poor plasma, and platelet rich plasma (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 bone marrow component layers by separating based on density of liquids.

The Procedure Pack has two models: BmSC+③ and BmSC+⑨, each with three volumes (60, 120 and 240 mL). The process kit includes the following components:

Process kit model	Components	Description
BmSC+③ 60 Process Kit /BmSC+⑨ 60 Process Kit	BmSC+③/BmSC+⑨ 60 Process Disposable (PD) (1 each)	Centrifuge barrel to separate bone marrow into layers In BmSC+③ and BmSC+⑨, Chamber 1: where bone marrow is injected Chamber 2: where cell concentrate is collected
	Blunt Cannula and Cap (1 each)	Extract platelet rich plasma (PRP) in the PD barrel after centrifugation.
	Blunt Cannula, Spacer and Cap (1 each)	Remove platelet poor plasma (PPP) from the PD after centrifugation to leave approximately 10 mL PRP.
	IN Blunt Cannula	Attach to the syringe and transfer the filtered bone marrow into the PD.
BmSC+③ 120 Process Kit /BmSC+⑨ 120 Process Kit	BmSC+③/BmSC+⑨ 60 Process Disposable (PD) (2 each)	Same as BmSC+③ 60 /BmSC+⑨ 60 PD.
	Blunt Cannula and Cap (2 each)	
	Blunt Cannula and Spacer (2 each)	
	IN Blunt Cannula	Same as BmSC+③ 60 /BmSC+⑨ 60 PD.
BmSC+③ 240 Process Kit /BmSC+⑨ 240 Process Kit	BmSC+③/BmSC+⑨ 60 Process Disposable (PD) (4 each)	Same as BmSC+③ 60 Process Kit /BmSC+⑨ 60 PD.
	Blunt Cannula and Cap (4 each)	
	Blunt Cannula, Spacer and Cap (4 each)	
	IN Blunt Cannula	Same as BmSC+③ 60 /BmSC+⑨ 60 PD.

B Instrument Description Information:

1. Instrument Name:

   SMART M-CELL 2 and SMART M-CELL 4

2. Specimen Identification:

   Sample identification label

3. Specimen Sampling and Handling:

   Bone Marrow collection should be performed in accordance with the standard operating procedures (SOPs) established at the bone marrow collection site.

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):	K250518	K052925
Device Trade Name	SMART M-CELL Bone Marrow Concentration System	SmartPReP2 Centrifuge System
General Device Characteristic Similarities		
Intended Use/ Indications For Use	The SMART M-CELL Bone Marrow Concentration System is intended to be used in the clinical laboratory or intraoperatively at point-of-care for the safe and rapid preparation of a cell concentrate from bone marrow.	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 Primary centrifugation: 2300 RPM Second centrifugation: 2200 RPM	Centrifugation Time: 14 minutes Primary centrifugation: 2500 ± 150 RPM 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 BmSC+③ 60 and BmSC+⑨ 60 kits with the SMART M-CELL 2 device at a single site. Bone marrow 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 samples and evaluated side-by-side between the subject and predicate devices. The results demonstrate that the SMART M-CELL Bone Marrow Concentration System is equivalent to the predicate device in preparing bone marrow 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 BmSC+③ 60, BmSC+③ 120, BmSC+③ 240, 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.