510(k) Summary

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Subject Device:	Precise Cell Concentration System
Regulation Number:	21 CFR 864.9245
Regulation Name:	Automated blood cell separator
Regulatory Class:	II
Predicate Device:	Precise Cell Concentration System

Indication for Use:

The Precise Cell Concentration System is designed to be used for the safe and rapid preparation of autologous platelet rich plasma (PRP) from a mixture of peripheral blood and bone marrow aspirate (BMA) at the patient's point of care. The PRP is mixed with autograft and/or allograft bone prior to application to a bony defect to improve handling characteristics.

Device Description

The Precise Cell Concentration System is a sterile, single-use kit comprising blood collection components, syringes, and the components necessary to process a mixture of peripheral blood and BMA samples. The sample collected is transferred to the processing cannister and placed into a general-purpose centrifuge. After centrifugation, the desired amount of PRP is isolated in the syringe. The device is built of medical-grade polymers, elastomer, and stainless steel, suitable for use in medical devices.

Technological Characteristics and Substantial Equivalence

The fundamental scientific technology, principles of operation, materials of construction, sterility assurance level, and biocompatibility are exactly the same between the subject Precise Cell Concentration System and the predicate device, BK200540. There are no technological characteristics that raise new issues of safety or effectiveness for how the cell concentration is generated compared with the Precise Cell Concentration System. Both the subject and predicate devices process 60 mL of anticoagulated samples. Both devices require the use of a general

centrifuge to separate the sample into layers based on cell density. The bottom layer generated is red blood cells (RBC), and above that is a buffy coat layer (white blood cells and platelets) and plasma. The RBCs are trapped under the buoy system within the Precise cannister. The buffy coat layer mixed with a small amount of plasma constitutes the final product. The following outlines the comparison of technological characteristics between the subject Precise Cell Concentration System and the predicate Precise Cell Concentration System.

Point of Comparison	**Predicate Device- Precise Cell Concentration System – BK200450**	**Subject Device- Precise Cell Concentration System - BK251168**
Indication for Use	The Precise Cell Concentration System is designed to be used for the safe and rapid preparation of autologous platelet rich plasma (PRP) from a small sample of peripheral blood at the patient's point of care. The PRP is mixed with autograft and/or allograft bone prior to application to a bony defect to improve handling characteristics.	The Precise Cell Concentration System is designed to be used for the safe and rapid preparation of autologous platelet rich plasma (PRP) from a mixture of peripheral blood and bone marrow aspirate (BMA) at the patient's point of care. The PRP is mixed with autograft and/or allograft bone prior to application to a bony defect to improve handling characteristics.
System Components	Disposable concentrating device packaged with syringes, blood draw needles, blood draw accessories, and ACD-A anticoagulant.	Disposable concentrating device packaged with syringes, blood draw needles, blood draw accessories, and ACD-A anticoagulant.
Device Material	Medical grade polymers, elastomers and stainless steel suitable for use in medical devices.	Medical grade polymers, elastomers and stainless steel suitable for use in medical devices.
Principles of Operation/ Method of Fluid Separation	Separation of blood based on density.	Separation of blood and bone marrow aspirate based on density.
Device Structure	Cylinder with internal buoy	Cylinder with internal buoy
Method of Processing	Centrifugation	Centrifugation
Centrifuge Device	General purpose centrifuge	General purpose centrifuge
RCF	3000 G	3000 G
RPM	4400	4400
Centrifugation Duration	12 minutes	12 minutes
Process of concentration and plasma Collection	Aspiration of platelet rich plasma and platelet poor plasma through a swabable Luer valve	Aspiration of platelet rich plasma and platelet poor plasma through a swabable Luer valve
Capacity	60 mL	60 mL

Performance Data

The following performance data were provided in support of the substantial equivalence decision:

Bench Testing:

A study was conducted to determine whether the Precise Cell Concentration System could produce PRP from a mixture of peripheral blood and BMA collected from healthy human donors. The PRP obtained from the device was evaluated for platelet count, platelet fold, platelet yield, white blood cell count, red blood cell reduction, and platelet function. The results demonstrate substantial equivalence between the Precise Cell Concentration System and the predicate device across platelet fold, platelet yield, red blood cell reduction, p-selectin expression with or without agonist, hypotonic stress response, and pH.

A comparative study evaluated the Precise Cell Concentration System PRP against saline for bone graft handling. It assessed cohesion with PRP versus saline. Results indicate better bone graft handling with the Precise Cell Concentration System PRP than saline.

Biocompatibility Testing:

Biocompatibility testing on the sample contacting materials of the device was conducted in accordance with ISO 10993-1, "Biological Evaluation of Medical Devices –Part 1: Evaluation and Testing within a Risk Management Process". The Precise Cell Concentration System is categorized as an externally communicating device with limited exposure (contact < 24 hours) with indirect blood contact. Testing included cytotoxicity, sensitization and irritation, acute systemic toxicity, material-mediated pyrogenicity, and hemocompatibility.

Sterilization and Shelf Life:

The Precise Cell Concentration System will be sterilized using (b) (4) irradiation following a validated sterilization process in accordance with ISO 11137-1:2006/ (R) 2015 (Sterilization of health-care products — Radiation — Requirements for the development, validation and routine control of a sterilization process for medical devices). The test was conducted to evaluate the structural integrity of the product packaging following worst-case conditioning, including two (2) times sterilization and post-simulated shipping and aging. The results demonstrated that the device's structural and functional integrity remains intact following conditioning, and the data support a 2-year shelf-life.

Conclusion

Performance testing and a comparison of characteristics between the subject and predicate devices have demonstrated that the Precise Cell Concentration System is substantially equivalent to the predicate device in terms of operation, function, and technological characteristics.