510(k) Summary

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Subject Device:	Precise Cell Concentration System
Regulation Number:	21 CFR 864.9245
Product Code	ORG
Regulation Name:	Automated Blood Cell Separator
Device Common Name:	Platelet and Plasma Separator For Bone Graft Handling
Regulatory Class:	II
Predicate Device:	GenesisCS Component Concentrating System (BK050055)
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.

Device Description

The Precise Cell Concentration System is a sterile, single-use kit comprised of blood collection components, syringes, and the components necessary for processing the blood sample. The collected blood sample is transferred to the processing cannister and placed into a general-purpose centrifuge. After centrifugation, Platelet Rich Plasma (PRP) is aspirated using a syringe. The device is built of medical grade polymers, elastomers and stainless steel suitable for use in medical devices.

Technological Characteristics and Substantial Equivalence

The fundamental scientific technology, materials of construction, processing methods and mechanism of operation are similar between the subject Precise Cell Concentration System and the predicate device. There are no technological characteristics that raise new issues of safety or effectiveness for how the Platelet Rich Plasma (PRP) is generated

compared with the GenesisCS Component Concentrating System. Both the subject and predicate devices process 60 mL of anticoagulated whole blood. Both devices require use of a general centrifuge to separate the blood 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 RBC layer is trapped under the buoy system within the Precise cannister. The buffy coat layer mixed with a small amount of plasma constitutes the final PRP product. The following Table 5.1 outlines the comparison of technological characteristics between the subject Precise Cell Concentration System and GenesisCS Component Concentrating System.

Table 5.1 – Technological Characteristic Comparison

Point of Comparison	**Predicate Device- GenesisCS Component Concentrating System - BK050055**	**Subject Device- Precise Cell Concentration System - BK200540**
Indication for Use	The GenesisCS Component Concentrating System is designed for the safe and rapid preparation of autologous platelet rich plasma (PRP) from a small sample of blood at the patient's point of care. The PRP can be mixed with autograft and allograft bone prior to application to an orthopedic surgical site as deemed necessary the clinical use requirements.	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.
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.
Method of Fluid Separation	Separation of blood based on density.	Separation of blood based on density.
Method of Processing	Centrifugation	Centrifugation
Centrifuge Device	General purpose centrifuge	General purpose centrifuge
Process of PRP/PPP 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
Sterile	Yes	Yes

Performance Data

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

Biocompatibility Testing:
Biocompatibility testing on the blood 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 device is categorized as an externally communicating device, with limited exposure (contact < 24 hours) with indirect blood contact. Testing included cytotoxicity, sensitization & irritation, acute systemic toxicity, material-mediated pyrogenicity, and hemocompatibility.

Bench Testing:
A paired, comparative study was conducted between the Precise Cell Concentration System and the predicate GenesisCS Component Concentrating System. Whole blood from healthy human donors was processed and PRP was collected for each device per the appropriate instruction-for-use. The obtained PRPs were evaluated for platelet concentration (count, fold and yield), platelet aggregation, hypotonic stress response, pH, and p-selectin expression. The results obtained support substantial equivalence of the Precise Cell Concentration System to the predicate device in all parameters evaluated.

Additionally, a paired, comparative study was conducted between the Precise Cell Concentration System PRP and saline for assessing improvement in bone graft handling. The results obtained support improved bone graft handling when hydrating with the Precise Cell Concentration System PRP as opposed to the saline control.

Sterilization and Shelf Life:
The Precise Cell Concentration device will be sterilized using 100% ethylene oxide Sterilant following a validated sterilization process in accordance to ISO 11135:2014 (Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices). Testing was conducted to evaluate the structural integrity of the product packaging following worse-case conditioning including: two (2) sterilization cycles, post-sterilization aging (accelerated and real time) and distribution simulation. The results demonstrated that the device's packaging structural and functional integrity remain intact following conditioning and the data supports a 1-year shelf-life for the device.

Conclusion

Performance testing and comparison of characteristics between the Precise Cell Concentration System and the predicate device support substantial equivalency with regards to intended use, operation, function, and technological characteristics.