5. 510(k) Summary

The following information is provided in accordance with 21 CFR 807.92 for the Premarket 510(k) Summary:

5.1 Submitter Information

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5.2 Name of the Device

Trade Name:	XCELL PRP™ Platelet Concentrating System 60ml
Common Name:	Platelet And Plasma Separator For Bone Graft Handling
Classification Name:	Automated Blood Cell Separator
Review Panel:	Hematology (HE)
Regulation:	864.9245
Class:	Class II
Product Code:	ORG

5.3 Equivalence Claimed to Predicate Device

The XCELL PRP™ Platelet Concentrating System 60ml is equivalent to the Centrepid Platelet Concentrator (BK130079), manufactured by Cellmedix Holdings, LLC. The reference device for this submission is GenesisCS Component Concentrating System (BK050055).

5.4 Device Description

The XCELL PRP™ Platelet Concentrating System 60ml is a single-use, sterile kit consisting of blood draw components, syringes, and a concentrating device. It concentrates blood components and aids in separation of the blood components by density through the use of its components, specifically the concentrating device, and a centrifuge. The Eppendorf Model 5702 was used for all performance testing; thus, it is to be used with the XCELL PRP™ Platelet Concentrating System.

The system prepares platelet rich plasma (PRP) from a small volume of blood that is drawn at the time of treatment.

The materials of the system's components consist of medical grade polymers, elastomers, and stainless steels suitable for use in medical devices.

5.5 Indications for Use

The XCELL PRP™ System is intended 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 the application to a bony defect for improving handling characteristics.

The Indications for Use of the subject device is nearly identical to the Indications for Use of the predicate device, the Centrepid Platelet Concentrator.

5.6 Comparison of Technological Characteristics

The fundamental scientific technology, materials, processing method, and mechanism of operation are similar between the subject XCELL PRP™ Platelet Concentrating System 60ml and the predicate and references devices. All devices are provided as sterile concentrating systems, designed to concentrate and aid in the separation of blood and preparation of PRP by density through the use of a centrifuge. All devices are made of medical grade polymers, elastomers and stainless steels suitable for use in medical devices.

All devices include a single-use, disposable receptacle (e.g., concentrating device) that is designed to accept a volume of 60cc of anticoagulated whole blood which then undergoes centrifugal processing in order to obtain platelet concentrate (PRP).

The subject device and the predicate devices all use a centrifuge to spin the anticoagulated whole blood into platelet rich plasma and platelet poor plasma. The Eppendorf centrifuge Model 5702 is to be used with the XCELL PRP™ Platelet Concentrating System 60ml. This is the same centrifuge which is to be used with the predicate Centrepid Platelet Concentrator. The reference GenesisCS Component Concentrating System can be used with a general use centrifuge.

Although the predicate device goes through two spin cycles and the subject device goes through only one spin cycle, this difference does not raise any questions of safety and effectiveness in the preparation of PRP. The reference device also goes through only one spin cycle, and performance testing confirmed that the XCELL PRP™ Platelet Concentrating System 60ml is substantially equivalent for platelet concentrate quality and characteristics.

5.7 Performance Data

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

Biocompatibility Testing:

Biocompatibility testing on patient contacting materials was completed in accordance with the requirements of ISO 10993-1: 2009, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. Components in the XCELL PRP™ Platelet Concentrating System 60ml are either categorized as externally communicating devices, with limited exposure (contact < 24 hours) with indirect blood or surface devices, with limited exposure (contact < 24 hours) with intact skin, and underwent biocompatibility testing according to their categorization. Results show that the device is biocompatible for its intended use.

Bench Testing:

A paired study evaluating platelet concentrate quality was conducted with the XCELL PRP™ Platelet Concentrating System 60ml and the reference GenesisCS Component Concentrating System using blood collected from healthy human donors for processing into platelet rich product. The following platelet concentrate quality tests were performed: blood cell counts, platelet concentration factor, platelet yield, pH, platelet activation, platelet aggregation, and hypotonic stress response. The results

obtained demonstrate substantial equivalence of the XCELL PRP™ Platelet Concentrating System 60ml to the reference device for all parameters evaluated.

Testing was conducted to determine if the platelet-rich plasma (PRP) produced by the XCELL PRP™ Platelet Concentrating System 60ml performs as therapeutically indicated by improving bone graft handling. The results demonstrate that the XCELL PRP™ Platelet Concentrating System 60ml perform equivalently to the predicate Centrepid Platelet Concentrator in the preparation of PRP which improves the handling characteristics of allograft bone materials.

5.8 Conclusions

Performance testing and comparison of technological characteristics between the XCELL PRP™ Platelet Concentrating System 60ml, the predicate Centrepid Platelet Concentrator (BK130079), and the reference Genesis CS Component Concentrating System (BK050055) has demonstrated that the XCELL PRP™ Platelet Concentrating System 60ml is substantially equivalent with regard to materials, intended use, operation, function, and technological characteristics.